This package of information follows the requests made at a meeting in Lausanne on November 15, 1991.

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SECTION 1: EPA RELATED MATERIALS

Section 1.1:

EPA Fails to Follow Formal Bidding Procedures

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This document is in the public domain and can be used by CA people to support arguments that the EPA has been dishonest in its handling of the ETS issue. Clearly, the EPA had a predetermined outcome in mind when it decided to review the statistical evidence concerning ETS and its potential effect on the health of non-smokers.

Section 1.2:

US Representative Asks EPA Some Tough Questions

US Representative Thomas J. Bliley is the ranking minority member of the oversight and investigations subcommittee of the Energy and Commerce Committee. Mr. Bliley has been highly skeptical of EPA and its handling of the ETS risk assessment.

This lengthy letter, addressed to Mr. William Reilly, head of EPA, questions many of the unusual procedures EPA followed in its risk assessment on ETS. For example, Mr. Bliley asks EPA why some of the largest studies on ETS (which showed no statistically significant increase of risk to non-smokers) were not included in their meta-analysis. Mr. Bliley also raises the point that in regard to evidence on animal studies (of which there was none), the EPA failed to follow its own internal risk assessment guidelines.

Perhaps the most compelling argument raised in Mr. Bliley's letter concerns the EPA's inconsistency in classifying certain substances as carcinogens. Mr. Bliley points out, for example, that the evidence reviewed by EPA in the past on diesel fumes and Electro-Magnetic Fields were arguably far more conclusive than that on ETS, yet EPA declined to make either a Class A Carcinogen, which is what they are recommending ETS be classified.

This letter is part of the public domain and can be used by CA people to illustrate that the tobacco industry is not alone in having very serious reservations about EPA's risk assessment on ETS. Clean copies of this document are available in your ETS REFERENCE MANUAL.

Section 1.3:

The Economist Criticizes EPA Priorities

This article basically accuses EPA, and William Reilly in particular, of chasing "low-damage, but high-publicity" cases. It criticizes EPA for acting more like a "cancer-prevention than Environmental agency."

This article supports the allegation that EPA is more interested in a political agenda than an environmental one. If you need more supporting evidence to make this case to interested parties, i.e. journalists or regulators in your market, PMCS can supply you with speakers, articles, videos and brochures.

Clean copies of this document are available in your ETS REFERENCE MANUAL.

Section 1.4:

Representative Bliley Makes Case on ETS Science
EMF's Handled Differently Than ETS

This first article, written by Representative Bliley, summarizes the main deficiencies in EPA's risk assessment on ETS and its attempt to classify ETS as a Class A Carcinogen.

It is an excellent article for CA people when trying to brief a non-technical person on ETS science. In addition, as the article is written by a US Representative, it clearly supports our claim that the EPA's methods are not globally accepted in US political circles.

I have also attached an article which appeared in the Lancet on EPA's handling of the Electro Magnetic Field issue. As you will see, the evidence on EMF was far "stronger" than ETS. Unlike ETS, however, scientists were quick to point out the speculative nature of the evidence on EMFs.

Section 1.5:

PMCS Briefing Paper on ETS and EPA

This short briefing paper on EPA summarizes opinions expressed by leading European scientists and official European bodies which fly in the face of EPA's conclusions. It also points out some of the deficiencies in EPA's risk assessment.

This document must still be revised. A final copy will be forwarded to you. In the meantime, it can be used to familiarize yourself with the generalities of EPA's review on ETS.

Section 1.6:

ETS: Rush to Judgement - A PM Brochure

This pamphlet is still being adapted for European audiences. The references to baseball, certain studies, and quotes will be changed to achieve a more "European slant".

Once the final changes have been made, a copy will be forwarded to you for translation into your local language(s). I will send you instructions to have the translations legally cleared and will be available to assure the quickest possible clearance procedure.

Once the translations have been cleared and the pamphlets printed, you will be free to use the brochure as you see fit. I would recommend, however, that the brochures be used to generate interest before the EPA's official announcement, now expected in late February or early March 1992.

Once the media interest has been generated, you can invite journalists to a full background briefing. PMCS can help supply you with specially adapted press briefing programs; our resources include Tom Borelli, Science & Technology, London visits through C&B, and Tony Andrade.

SECTION 2: WHAT OTHER EUROPEAN BODIES HAVE SAID ABOUT ETS

Section 2.1:

Executive Summary of the Health Council - Netherlands

In 1990, at the request of the Dutch government, the Dutch Health Council reviewed the scientific evidence on ETS to ascertain whether ETS is harmful to health. Although not entirely positive, the Council found the following:

- The evidence on ETS is mainly statistical and is beset by methodological problems.

- Occasional exposure to ETS is an inevitable concomitant of people's social lives.

- Quantitative estimation of the additional lung cancer risk of non-smokers exposed to tobacco smoke is not possible at present.

- On cardio-vascular disease: The Committee does not expect short-term exposure to tobacco smoke to affect the circulation of healthy non-smokers in normal circumstances.

- The Committee's conclusion that ETS is harmful to health is primarily based as a result of tobacco smoke's "smell and irritating effects".

Section 2.2:

UK Government Response to Report on Indoor Pollution

Unfortunately, the UK government response to the House of Commons Report on Indoor Pollution (1991) did not consider the scientific evidence on ETS as objectively as the Netherlands. The government accepts that "breathing sidestream smoke causes a small increased risk of lung cancer.." (page 7).

The government recommends that non-smoking becomes the norm in the workplace and that separate, well ventilated areas be set aside for smokers. The government's policy is to promote workplace smoking policies and smoking restrictions in public places.

The Health and Safety Executive (HSE) will start a campaign on the need to segregate smokers and non-smokers in public buildings and will consider the need to update its current guidance on workplace smoking policies (page 5). We know that the HSE has already been pressuring important groups of employers to ban smoking completely in their workplaces.

If a similar report on ETS or IAQ exists in your country, please send me a copy at PMCS.

This UK report clearly illustrates one danger we are not always ready to counter. The danger exists that workplace smoking will be attacked through the national regulations of the safety and health agencies. The result, in the long term, will be similar to a legislated smoking ban, only governments will not have to face the political repercussions of such an unpopular law. Please make sure you have a good understanding of the position and actions undertaken by your national workplace safety and health agencies.

SECTION 3: EC ACTIVITIES WITH IMPACT ON ETS ISSUES

Section 3.1:

Analysis: Safety & Health Directives (Executive Summary)

One of the EC's main objectives is to harmonize the different laws concerning Safety & Health at the Workplace. Several directives already have passed which either have or could have an impact on workplace smoking:

1) Directive 89/654 - Minimum Safety and Health Requirements in the Workplace. This directive requires all member states to adopt certain minimum S&H standards and has a direct impact on smoking at work. The directive requires all workplaces used for the first time after January 1, 1993, and all workplaces renovated after that date, to take appropriate measures to protect non-smokers against discomfort caused by tobacco smoke in rest areas.

2) Directive 89/391 - The Third Action Program Concerning Safety & Health at the Workplace. Article 6 of this directive imposes a general requirement on employers to implement protective measures to avoid risks and, when they cannot be avoided, to combat risks at their source.

Article 11 gives employees the right to ask an employer to take appropriate measures and to submit proposals to him to mitigate hazards for workers and/or to remove sources of danger. Obviously, if ETS becomes perceived as a real risk or health hazard in the workplace, employers could be legally obligated to take action against the risk.

3) Other directives which could be of concern, depending on how they are written and applied, are directives regulating dangerous substances, protection of pregnant women, and the schedule of recognized occupational diseases.

The provided executive summary is confidential, please do not share it with anybody outside the company without legal approval from Hugh Brass. An accompanying analysis is updated regularly and EC developments are closely monitored. If you have any questions or need the complete analysis, please contact Hugh Brass or myself at PMCS.

If you decide to analyze your own national safety & health regulations and their potential impact on workplace smoking and employer responsibilities, please communicate your findings to Hugh Brass and myself at PMCS.

Section 3.2:

1992: EC Year of Safety, Health, and Hygiene at Work

The attached information includes all the relevant information we have on the Year of Safety and Health at work, it includes:

1) **The Council Decision published in the Official Journal on the objectives and procedures for the Year of Safety & Health.**

2) **An application form for projects to be considered by the EC to be part of the official program.** These applications must be filed through national committees. If you have an idea for a project which could be submitted, please contact me at PMCS or Chuck Lister at Covington & Burling.

3) **The official program for the Belgian Year of Safety & Health activities.** Although smoking is not specifically mentioned, IAQ problems are considered one of the leading themes. As you know, IAQ discussions are often disproportionately concentrated on smoking and ETS. In addition, the above mentioned directives (section 3.1) make unbalanced presentations on ETS of particular concern.

It would be extremely useful if you can procure the official program of your national market as regards to the Year of Safety & Health. The responsible national liaison committees are listed on the second to last page of the application (point 2 above). Please communicate any information you are able to discover to me at PMCS as it would be most useful in our efforts.

Section 3.3:

1989 EC Resolution to Ban Smoking in Public Places

In 1989, the EC Council voted unanimously on a non-binding resolution that would severely limit the places where people can smoke. This section includes the resolution and a French article which describes the EC's probable next steps on this issue.

As you will see from the article, the EC is waiting on a "progress report" from each member state. It would be very useful if you can ascertain whether your national government has already submitted this status report and, if yes, procure a copy of it.

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Section 3.4:

Effects of EC Safety & Health Legislation

The attached article from a national UK daily paper describes some of the tough requirements imposed by Brussels on employers. The subject here is computers rather than smoking, but one can quickly see how seriously the EC considers the subject. When the EC decides to attack smoking at the workplace, it is unlikely that they will be anymore sympathetic than they have been to computers.

Section 3.5:

Europe Against Cancer - A Review of 1990

This very long and in-depth analysis of the measures taken by the EC under the Europe Against Cancer program is available from PMCS. Attached are some examples of the information it contains.

It is obvious from the quality of the publication that the EC considers Safety & Health as one of its top priorities and is giving it the financial backing they feel it deserves. Required reading if you want a good historical understanding of the program.

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SECTION 4: BOOKS

Section 4.1:

Book Review of "Other People's Tobacco Smoke"

This book review printed in Occupational Safety & Health gives 5 stars to the book, Other People's Tobacco Smoke. The book is a compilation of articles by leading people in their field. The subjects range from the statistics behind "ETS science" to the sociological aspects of smoking.

The book, which Philip Morris helped make possible, is available for your use. If you would like individual chapters or the whole book translated to your language, please let me know.

The book should be used to garner interest on the subject of ETS and can be promoted to as great an extent as is appropriate for your market. In addition, although the authors of the book are independent professionals in their field, each one could be invited to speak at a press briefing if you should wish it. If you would like invite one of the authors to speak in your market, please contact me at PMCS.

Section 4.2:

Dr. Petr Skrabanek's "Follies and Fallacies in Medicine"

The attached article resulted in part due to an interview with Dr. Petr Skrabanek. Dr. Skrabanek wrote a book called Follie and Fallacies in Medicine.

This highly serious, yet humorous and easy to read book puts into question some of the most fundamental assumptions in modern medicine. One cannot read it without becoming enthralled and, in some cases, scandalised.

The book is being translated into several languages. Perhaps Dr. Skrabanek would be willing to speak at PM organized gatherings such as a press briefing to discuss his book. If you are interested, please contact me at PMCS.

(You can also find a great article by Dr. Skrabanek in the ETS REFERENCE MANUAL in the articles folder: science section)

SECTION 5: VIDEOS

Several videos exist for your use. Some have been prepared by PM and others are copies of broadcast news:

1) The Air We Breathe: This video on Indoor Air Quality exists in 5 minute and 20 minute versions. Language: English, French, German, and Italian. Copies will be sent to you under separate cover.

2) Science: The script for this video is attached and was reviewed at our meeting in Lausanne. As soon as the video is finished, a copy will be sent to you. Concerning some of the comments about this video, the second video being prepared for release will be very different from the presentation piece you will receive.

This video should be very useful when discussing EPA's shortcomings as an agency to assess health risks.

3) People and Numbers: This video, frequently used in S&T presentations illustrates some of the faults of statistics and how we must be very careful when trying to interpret the meaning of some statistical studies. Copies will be sent under separate cover.

4) WHO and Air Pollution: Swiss television ran a news story concerning an alleged WHO cover-up on environmental pollution. A copy will be forwarded to you shortly.

5) American Extremism: This short video compiles recent US news clippings and shows how extreme the Americans have become on the smoking debate. Its external use is debatable and would not be appropriate for non-English speakers, but with some imagination, it could be useful. Copies will be sent under separate cover.

SECTION 6: AIRLINES

Section 6.1:

Balair Courteous Smoking Advertisements

The attached advertisement has been a regularly running ad in Balair's in-flight magazine. The ad assures passengers that Balair's ventilation is run at full efficiency and calls on smokers to be considerate and non-smokers to be tolerant.

This novel approach to the smoking issue aboard aircraft has been an unprecedented success. Balair is the Swiss internal airline and a subsidiary of Swissair, one of the highest quality airlines in the world. If it works for Balair, perhaps it can work for your national carrier. If you are interested in pursuing such an initiative with your airline and would like more information, please contact Ulrich Crettaz at FTR.

Section 6.2:

Health Risks in Aircraft - Institute of Air Transport

This article by Larry Holcomb appeared in the publication of the Institute of Air Transport, an official airline industry organization. Mr. Holcomb explores different pollutants in the aircraft cabin, including ETS. He concludes that ETS is unlikely to pose a measurable health risk to passengers or flight attendants.

Mr. Holcomb also states that, "those whose travel has included major cities like Los Angeles, Tokyo and Sydney will appreciate that the airliner cabin environment is clean in comparison with that accepted in cities as the practicable limits to achieving clean air."

SECTION 7: RESTAURANTS

Section 7.1:

International Horeca Against Smoking Bans

International Horeca, based in Zurich, groups together restaurant associations from around the globe. At their recent annual conference in Budapest, members discussed environmental issues facing their industry. Smoking was also discussed and is considered an issue in countries as diverse as Spain, India and Egypt.

Interestingly, members of the conference signaled a desire to work more closely with national industry groups such as tobacco NMA's and/or large multinational companies with complementary interests. If you do not have a formal contact with the restaurant association in your country, we can supply you with the name of the relevant person. I am sure that they would be happy to hear from you and develop a program which supports their desire to handle smoking in ways other than legislation.

International Horeca has produced a kit on the question of smoking in restaurants. A portion of the kit is enclosed. This kit was sent to members of International Horeca around the globe. Please contact PMCS for a full copy of the kit in English, French or German.

SECTION 8: SURVEYS

Section 8.1:

French Restaurant Polls

In March, when the French government decided to move ahead with its plans to ban smoking in workplaces and restaurants, PMF decided to measure the popularity of such a law. PMF asked the research firm, RES, to run consumer research analyzing people's behaviors and views towards restaurants.

The questionnaire was reviewed with the French restaurant association beforehand because much of the resulting information would be of value for their strategic planning and useful to their members.

PMF disseminated the results in a press conference. At the press conference, PMF also presented a video it had commissioned which showed famous French chefs deploring the idea of legislated smoking bans. The survey and the video resulted in significant television and press coverage. Some articles and translations are attached.

An executive summary of the results is attached along with some of the resulting press coverage which was entirely positive. An English translation of the survey results will be forwarded to you, but if you would like more details on the whole operation, please contact Frank Farnel at PMF or myself at PMCS.

Section 8.2:

French Workplace Study

At the same time as PMF commissioned the restaurant survey, it commissioned a survey on workplace. Again, all major unions were contacted beforehand to ask for their input. After the suggestions of the unions were incorporated into the survey, the study was launched.

The results of the survey were shared with all the unions and a special report created for them. The survey results were then made public by PMF at a press conference. A video was also shown in which famous labor leaders and employers expressed their concern over legislated smoking bans in the workplace.

The survey and video resulted in significant press coverage. PMF was never attacked for commissioning the surveys and press coverage was clearly accepted our messages. Some articles and translations are attached with the summary of the survey findings. An English translation of the summary will be forwarded.

If you would like more information on this subject, please contact Frank Farnel at PMF or myself at PMCS.

SECTION 9: NEW STUDIES

Section 9.1:

New US ETS Study - A Critique

UK press paid attention recently to an ETS study being conducted in the USA. It is claimed to be the largest such study to date, but the study is not yet finished.

Attached is a paper on the study which appeared in a US epidemiological journal and a an initial critique of that paper.

SECTION 10: PM MATERIALS

Section 10.1:

Fresh Air in the Workplace - A PM Brochure

The attached brochure exists in French, English, Spanish and Portuguese. If you would like additional copies, please contact me at PMCS.

Section 10.2:

ETS Position Paper

The attached document is the preliminary official position of PM-EEC (and hopefully EEMA soon) on the subject of ETS and smoking restrictions. Although EEMA has yet to give its final comments, I thought it would be useful to distribute now.

The comments made by EEC CA managers have been incorporated into the text and clearance has been given by legal and top management. If you have any last minute revisions you would like to include, please let me know as soon as possible.

In the coming weeks (hopefully), a final version in your local language will be forwarded.

Section 10.3:

Sales Force Training of CA Issues

As most of you know, PMCS has developed a presentation for the Italian sales force addressing the main CA issues like Smoking & Health, ETS, Labelling, etc. The presentation is a narrative combined with video footage.

Attached is the legally approved text. The video is available at PMCS. If you are interested in adapting this presentation for your market, please contact Sean Murray at PMCS. Also keep in mind that any changes to the presentation must be legally approved by Hugh Brass and Tony Andrade (PM-EEC). PMCS will gladly assist you in adaptation and legal clearance procedures.

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SECTION 11: MISCELLANEOUS

Section 11.1:

Articles on ETS from European Medical Journals

Attached are a selection of articles from recent medical journals in France and Italy. The articles refer to different aspects of ETS and IAQ and are mostly in agreement with the arguments we put forward.

Feel free to use them as may be useful and if you are interested in generating similar articles in your market, please contact me at PMCS. Should similar articles be published in your market, please forward them to me so that people in other markets can make use of them.

Section 11.2:

Employer Liability

As you know, there have been cases in Europe where employees have collected monetary settlements based on the claim that ETS has harmed their health. These cases, while unique, understandably cause significant concern among employers. Such concern can lead to workplace smoking bans if not addressed.

The likelihood and bases of compensation awards vary according to national occupational insurance programs. Attached is a 1-year old analysis for your market(s).

Based on the developments in your market, you may wish to sponsor a seminar or briefing to personnel associations or employer unions. Should you wish to proceed with such a program, please check with EEC legal department first. PMCS is also able to assist you in such an endeavor.

Some of you expressed concern about who was monitoring developments in this field. I will confirm the exact procedure at a later date. In the meantime, if you have any questions or comments, please contact Hugh Brass, Tony Andrade or myself.

Section 1.1:

EPA Fails to Follow Formal Bidding Procedures

The attached statement by US Representative Thomas Bliley summarizes his case against EPA. Among his allegations, Mr. Bliley claims that the EPA failed to follow federal procurement laws when it awarded a contract to the Smoking Policy Institute, a well-known anti-smoking group. He also criticizes the EPA for issuing a smoking policy document before finalizing its scientific review on ETS.

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THOMAS J. BLILEY, JR.
7TH DISTRICT, VIRGINIA

MEMBER OF:
COMMITTEE ON ENERGY AND COMMERCE
COMMITTEE ON THE DISTRICT OF COLUMBIA

Congress of the United States
House of Representatives
Washington, DC 20515-4607

WASHINGTON OFFICE:
2241 RAYBURN OFFICE BUILDING
(202) 225-2815

DISTRICT OFFICE:
SUITE 101
4914 FITZHUGH AVENUE
RICHMOND, VA 23230
(804) 771-2809

Statement of Rep. Thomas J. Bliley, Jr.
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
November 12, 1991

Mr. Chairman, this subcommittee has conducted a lengthy investigation on the issue of scientific fraud which showed that researchers have reported findings that were unsupported by the evidence and that the evidence itself was manipulated.

These revelations were disturbing to this Member and, I am certain, to everyone on this subcommittee. Just recently, Mr. Chairman, I noted that you were quoted in the local press expressing your concern over why a controversial critique of scientific work on a controversial subject was ignored by EPA.

The Clean Air Act Amendments placed an important responsibility on the EPA to conduct scientific evaluations of 189 chemical compounds. It is imperative that these evaluations be based on the best, most complete science available and that the process of evaluating them be free from bias.

The American people must be able to rely on their government for accurate information on countless matters that are essential to their economic and social well being. The integrity of the scientific process is critical to everyone. If individuals running that process can manipulate it for their own purposes then no one is safe.

The bedrock principle of our democracy is that we are a government of laws, not of men. It is contrary to our very system of government for a government agency to flout the law by preordaining the result it wants to reach and then rigging the process to get there.

It is wrong when federal procurement regulations are trampled and a contract is sole-sourced in clear violation of the law.

It is wrong for the government to jump the gun and issue a policy document built on the results of a scientific study that has not yet been finished.

And that wrong is grievously compounded when an agency launders a contract to parties who have known bias on the research in question and stand to reap a financial windfall if the taxpayer-funded study they are conducting comes out a particular way.

I know Mr. Reilly shares our view that the principles of fairness and objectivity must govern the conduct of government business. Unfortunately, I am concerned that his agency's performance in this area often has not matched his commitment to these principles.

As you know, I have been deeply troubled by EPA's handling of a number of issues, including environmental tobacco smoke. The investigation of this particular issue clearly shows that the agency has violated each and every one of the principles

I have just outlined.

First, EPA completed a draft policy guide on workplace smoking -- a subject on which it lacks both jurisdiction and expertise -- prior to the time the agency finished its own risk assessment on ETS. When I suggested a year and one half ago that it made sense to complete the risk assessment before writing a policy guide, my staff was told that my suggestion was not practical since the risk assessment was still being completed and the policy guide was already done.

The policy guide, among other things, recommends a ban on workplace smoking. Yet, EPA has never, in its ETS Risk Assessment or any other agency document, evaluated the data on workplace smoking. And after more than two years of wasting agency resources and substantial sums of the taxpayers money EPA officials have admitted as recently as this past summer that they know little about the subject.

Second, the Smoking Policy Guide was drafted by an organization called the Smoking Policy Institute, a group the Boston Globe identified as one of the major anti-smoking organizations in the country. This Institute is in the business of urging companies to implement smoking bans and gets paid for helping them to do so. Thus, a firm with a clear financial interest in the outcome was placed in a position to turn its private views into government policy without the intrusion of scientific evaluation of relevant workplace data and with the stamp of approval of EPA. You might think the EPA officials who originally solicited SPI for this project would question the appearance this contract might create.

Quite the opposite occurred. The EPA apparently chose to violate federal procurement law to make sure that the Smoking Policy Institute got the contract. I think it only fair to note that the initial award of this contract took place prior to Mr. Reilly becoming Administrator.

Mr. Chairman, I intend to ask the General Accounting Office to evaluate the fashion in which this contract was awarded without any competitive process. I am concerned that this method of laundering contracts through a general contractor to avoid the competitive process may be standard operating procedure at EPA. Clearly, in this instance, the subcontractor was directly solicited by the agency and the very next month selected by the general contractor to write this policy guide. Even if it passes the technicalities of a legal test, which I do not believe it does, it sure flunks the smell test on all counts.

When the process is short circuited in this fashion it raises great concerns as to the completeness and the integrity of a policy outcome. I look forward to working with you in our oversight capacity to insure that the process is both fair and complete and that agency science is complete and as unbiased as possible.

Section 1.2:

US Representative Asks EPA Some Tough Questions

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This lengthy letter, addressed to Mr. William Reilly, head of EPA, questions many of the unusual procedures EPA followed in its risk assessment on ETS. For example, Mr. Bliley asks EPA why some of the largest studies on ETS (which showed no statistically significant increase of risk to non-smokers) were not included in their meta-analysis. Mr. Bliley also raises the point that in regard to evidence on animal studies (of which there was none), the EPA failed to follow its own internal risk assessment guidelines.

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This letter is part of the public domain and can be used by CA people to illustrate that the tobacco industry is not alone in having very serious reservations about EPA's risk assessment on ETS. Clean copies of this document are available in your ETS REFERENCE MANUAL.

THOMAS J. BLILEY JR.

Congress of the United States

House of Representatives

Washington, DC 20515

May 9, 1991

The Honorable William Reilly
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

Dear Mr. Reilly:

Nearly one year ago, I first expressed my concern as the Ranking Minority Member of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce over the manner in which EPA was proceeding on three documents related to Environmental Tobacco Smoke [ETS]. As I have indicated previously, my concern goes far beyond that of ETS to the overall process by which the Agency conducts risk assessments. In light of the responsibility given to the EPA by the Clean Air Act, it is essential that the agency conduct its scientific analysis in a fair and consistent manner. If the ETS risk assessment is representative of EPA's capability of dealing with complex scientific issues in an objective fashion in accordance with its own guidelines, I fear the responsibility entrusted to the EPA by Congress may be misplaced.

While I have appreciated your attempts to respond to my concerns, I must in all candor indicate that those concerns are greater today than they were a year ago. As I result, I feel compelled to continue and expand my inquiry on this matter.

On April 10, 1991, Deputy Administrator F. Henry Habicht, II appeared before the Subcommittee on Health and Environment of the Committee on Energy and Commerce at a hearing on the Indoor Environment. Mr. Habicht's testimony covered in detail EPA's activities on indoor environment issues. Included in his testimony was the statement that EPA "has two major informational documents in preparation on ETS at the present time." [Page 13 of prepared statement.] Based on the statement I asked Mr. Habicht if "the technical compendium that was being worked on at one point has been dropped and will not be completed?" To my surprise, Mr. Habicht stated "[t]hat is on a separate track. I can't say right now what the schedule or precise outcome of that is going to be, but it's not on the same track as the risk assessment and policy guide."

Frankly, I'm a little confused. *Please explain how the agency could maintain in its prepared testimony that was presumably prepared with the assistance of those working on these projects that there were two documents in preparation and then indicate that a third document was proceeding on a "separate track?"*

In fact, this morning the Agency only added to the confusion when Michael Shapiro, Deputy Assistant Administrator for Air and Radiation, told the Subcommittee on Environment of the Committee on Science, Space, and Technology that EPA "has two major informational documents in preparation on ETS at the present time." [Page 14, prepared testimony of Michael Shapiro]

Deliberately providing false information to Congress is a serious matter. I hope that is not what is going on here. I find it troubling that the Agency appears "to be all over the map" on this matter. *Was Mr. Shapiro incorrect in his prepared testimony or did Mr. Habicht, after consulting with an employee of the Indoor Air Division, supply a false answer to my question?*

This is particularly troublesome in light of the fact that when EPA began this entire project the third document, the technical compendium, was supposed to form the basis for at least one of the other two documents, namely the policy guide.

A review of Agency documents seems to indicate that there is no consistent view of what role the technical literature compendium plays if any. Early in the process the policy guide was referred to as a simplified version of the compendium. Importantly, the SAB's draft report makes the point that it could not vouch for many of the statements in the policy guide because no supporting documentation was provided.

> Furthermore, there were statements about cardiovascular mortality, cancers at other sites, and aggravation of cardiovascular and respiratory disease that were not addressed in the ETS Risk Assessment. Thus, without having any supporting documentation, the Committee could not endorse these statements.
>
> The Policy Guide draft will need to be revised to reflect the changes that are being made in the Risk Assessment. If the Committee is to review the Policy Guide again, it should be sent to the Committee with a supporting document that explicitly states the technical basis for each of its summary statements on the state of scientific knowlege. [Page 42, draft SAB Report]

The passage quoted above indicates that the SAB felt the need for further documentation of many of the statements in the Policy Guide. *What led the Agency to redefine the role of the technical compendium?*

In July 1990, you responded to my letters dated May 17 and June 6, in which you indicated that

> [t]he technical compendium has undergone a limited external peer review and its chapters are now being revised to incorporate changes. When those revisions are completed, the cooperating organizations will discuss the appropriate next steps to take in ensuring that the document is a fair review of the existing technical information available on ETS. Those discussions could result in significant modifications to both the scope and content of the document. In addition, EPA's Science Advisory Board will also be given an opportunity to review this document before it is finalized.

Please describe the nature, extent and scope of subsequent discussions among the cooperating organizations on this document. Do you stand by your previous commitment to me that this document will also be reviewed by the SAB?

During the hearing, I also asked the Deputy Administrator if he believed "it important that the Agency's risk assessment work include the most up-to-date scientific research in the field." He indicated he did and I proceeded to ask him if he would be "disturbed to learn that a member of the SAB panel was in the process of publishing the largest study ever done on an issue he was reviewing that reached the opposite conclusion and never even bothered to raise that research during the panel's deliberations." Mr. Habicht responded that "[t]he kind of fact situation you pose would certainly be of relevance to the nature of the scientific outcome of a process."

I proceeded to outline to the Deputy Administrator that just such a situation had occurred. Dr. William Blot, a member of the SAB panel, published in December 1990 such a piece of research with Wu-Williams. My staff has reviewed thoroughly the transcript of the December 4 and 5 SAB panel meeting and found that Dr. Blot failed to disclose this research. *Do you believe it was appropriate for a review panel member to fail to reveal research of this significance?*

In response to the subsequent question, "what steps will you take to ensure that EPA updates the risk assessment using this and other recent data that are now available?", the Deputy Administrator stated "if there are significant new studies we certainly want to look at them and see how significant they are and how much they add to the process.... Any significant new study we would want to take a look at and assess it at least briefly before we issue a final report."

Asked if he would "be concerned if inclusion of recent studies in the risk assessment meta-analysis using EPA's own methodology changed the risk factor to a level that was statistically insignificant", he indicated he would "be interested in

that fact and knowing what is behind it..." *To date, what steps has EPA taken to follow up on the Deputy Administrator's commitment?*

My staff informs me that there are currently at least four studies whose data are not factored into the draft risk assessment. Copies of those four studies are enclosed with this letter. *Please have the staff of the Office of Research and Development [ORD] perform meta-analysis calculations employing the same methodology used in the draft risk assessment, which (1) include the four published studies I have supplied in addition to the research included in the calculations contained in the Draft Risk Assessment; and (2) have ORD perform separate meta-analysis calculations for U.S. and foreign studies contained in (1). Please supply the results of those meta-analyses to me.* I understand that this is a relatively straightforward mathematical calculation that takes little time to perform.

Please note that the Sobue study was referenced by one of the documents reviewers in his December SAB presentation [A. Judson Wells, page R4]. Also, last year my staff was informed that the only reason the Janerich data were not included in the risk assessment calculations was that the data were unavailable at the time. The Janerich publication was discussed in the risk assessment as the "Varela" study, which existed at the time the draft risk assessment was written as a doctoral dissertation from Yale.

Another of the four studies to which I refer -- Shimizu -- was mentioned by the Agency in the risk assessment, but not included in the EPA's meta-analysis of spousal smoking studies. The authors of the risk assessment stated in the document that these two studies [Varela/Janerich and Shimizu] were not included in the meta-analysis because of lack of "raw data" which would fit the statistical technique they chose for the meta-analysis. Staff informs me, however, that the Woolf method -- which was used in the risk assessment to combine the results of case control studies with cohort studies -- can accomodate the results presented in these two studies.

In addition to the four studies referred to above I have enclosed an abstract from another study by X. He and co-authored by R.S. Chapman. I believe Dr. Chapman is either a current or former EPA employee so there should be no problem in EPA obtaining this data if it chooses to do so. Additionaly, I note that X. He has been recognized in the past by EPA for his work in this area.

In performing the new meta-analyses calculations requested above, did any of the meta-analyses show a statistically significant relationship?

At my direction, my staff attended the April 18 meeting of the SAB Executive Committee meeting during the time period the ETS risk assessment review was discussed and during the discussion of EPA's plans to revise its Risk Assessment Guidelines over the next two years. The report and transmittal letter which the Executive Committee agreed to forward to you raised several important issues that I would like you to address.

The Charge to the SAB panel asked "[h]as EPA met the requirements stated in its carcinogen guidelines for characterizing ETS in category A, i.e., is the evidence sufficient to conclude that ETS is causally associated with lung cancer?" [Page 2, Memorandum from William Farland and Eileen Claussen to Robert Flaak, dated November 1, 1990.] While concurring with the draft assessment's conclusion, the transmittal indicates that the Committee "had some difficulty in applying the Guidelines for Carcinogen Risk Assessment (51 FR 33992), as they are currently formulated, to this complex and variable mixture." *While recognizing the need for some flexibility, do you believe it is appropriate to apply the Agency's own guidelines in an inconsistent and incomplete fashion?*

My concern in this area was increased by several reported comments by Dr. Lippmann and others at the Executive Committee meeting on this subject. For instance, one member of the SAB Executive Committee commented that in explaining that the SAB had difficulty applying the guidelines as written, it sounded a little like they were saying "if the data doesn't fit the guidelines, the guidelines should be changed."

> If the Guidelines for Carcinogenic Risk Assessment can be used to cast doubt on a finding that inhalation of tobacco smoke by humans causes an increased risk of lung cancer, the situation suggests a need to revise the Guidelines. [Page 28, draft SAB report]

I am sure you agree that changing the rules to fit a particular purpose or accommodate a particular point of view defeats the entire purpose of the guidelines. As you know, the guidelines "set forth the principles and procedures to guide EPA scientists in the conduct of Agency risk assessments..." *What procedures does EPA employ to ensure that its scientists conduct risk assessments in accordance with these guidelines?*

My staff sought to explore the applicability of the guidelines' definition for classification as a Class A with Dr. Lippmann at the public session for press and public following the Executive Committee meeting. On three separate occasions, my staff asked Dr. Lippmann, "if one were to apply the guidelines as written, could you classify ETS as a Class A known human carcinogen?" On all three occasions, Dr. Lippmann failed to respond to the question.

Ironically, without the press attention present the previous day, Dr. Lippmann did answer the question the next day. During the discussion period on the procedure for revising risk assessment guidelines, Dr. McClellan expressed the need to keep guidelines as guidelines with the flexibility to bring together risk assessment scientists and the cancer community. In response to that comment Dr. Lippmann indicated his agreement and raised the ETS review that had just been completed. He said that in ETS and Arsenic you had two such examples, because if you were to rigidly apply the guidelines then there was "no clear mechanistic basis for calling them carcinogenic."

EPA's existing guidelines do provide flexibility. In point of fact, that is the logic behind the concept of "weight of evidence." The guidelines "emphasize broad, but essential aspects of risk assessment...," yet seek "to permit sufficient flexibility to accommodate new knowledge and new assessment methods as they emerge." [51 FR 33993]

A cursory review of the risk assessment guidelines, the December 4 & 5 meeting transcript, the risk assessment itself, and the draft letter and report of the SAB Executive Committee provide interesting insight into the degree to which EPA failed to adhere to its own guidelines. Indeed, it appears that this is not a matter of minor deviation from the guidelines but the wholesale ignoring of them in the preparation of this risk assessment.

The EPA Draft Risk Assessment failed to apply a "weight of the evidence" approach to the scientific literature on ETS as called for by the EPA guidelines. Please supply answers to the following questions:

Why did the EPA and SAB reports neglect to review and articulate the scientific literature on actual ETS exposures? [Such an assessment is necessary to satisfy the guidelines' requisite for an exposure assessment.]

Why is "spousal smoking" considered an accurate exposure index when every epidemiological study published to date uses a different formula for defining spousal smoking exposure?

The dose-response evaluation for the epidemiologic studies was incorrectly applied in the EPA Draft Risk Assessment, yet no mention of this is made in the SAB report. *Can you explain why? Were you aware of this?*

The "hazard identification" reported by the EPA Draft Risk Assessment did not consider the literature on animal inhalation studies on sidestream smoke, or

any short term tests for mutagenicity, sister chromitid exchange, etc, in humans. *Does the literature in this area support such a Class A classification?*

Why has the EPA not reviewed the scientific literature to determine whether those constituents of sidestream smoke identified as "carcinogens" have been demonstrated to induce pulmonary cancer via inhalation in animal models?

The 1986 Surgeon General's report, the 1986 NAS Report, and much of the current literature recognizes that mainstream smoke, sidestream smoke, and ETS are physically and chemically distinct. The NAS is replete with statments to that effect. "Because the physiocochemical nature of ETS, MS, and SS differ, the extrapolation of health effects from studies of MS or of active smokers to nonsmokers exposed to ETS may not be appropriate." [Page 8, NAS Report] "The health implications to nonsmokers of exposure to ETS may not be a simple extrapolation from the studies of active smokers." [Page 20, NAS Report] "The dose of smoke delivered to the lungs of nonsmokers exposed to ETS is both qualitatively and quantitatively different from mainstream smoke, being a small fraction of that delivered to the lungs of an active smoker." [Page 184, NAS Report]

Why does the EPA draft and SAB report maintain that mainstream smoke and ETS are essentially equivalent?

The SAB noted that the Draft Risk Assessment relied almost exclusively on epidemiology. *Would it be appropriate for EPA to exclude recently published significant studies in updating the risk assessment [specifically, the Sobue, Janerich and Wu-Williams studies]? If it would be appropriate to exclude them, please provide a detailed explanation of why their inclusion is inappropriate and how they differ from studies that are included in the draft risk assessment meta-analysis?*

Why was workplace smoking exposure ignored in the EPA and SAB reports when several studies on spousal smoking also include information on workplace exposure?

If the epidemiologic results on spousal smoking are compared to a dose-extrapolation from active smoking to exposure to ETS in the nonsmoker, the difference in risk is of several orders of magnitude. *If EPA considers mainstream smoke to be "equivalent" to ETS and can be equated for the purposes of hazard identification, why is the dose-extrapolation model not urged by EPA nor the SAB to estimate the extent of risk?*

At least 25 studies examine the role of exposures other than ETS in childhood respiratory disease. These studies are listed in the EPA/IAQ literature index, yet they were neither reviewed nor included in the EPA draft or the SAB report. *Why were they excluded?*

How does the EPA justify its classification of ETS as a Group A carcinogen based solely upon uncritical acceptance of weak association epidemiology, to the exclusion of data which do not support its recommendation, i.e., actual exposure studies, studies on confounders, studies on tobacco smoke chemistry, studies on animal inhalation of sidestream smoke and short-term tests in humans?

Recent draft risk assessments on EMF and diesel exhaust considered all available published data on animals and on humans. The draft risk assessment on ETS appears deficient on both counts. Reported relative risk for humans exposed to EMF or diesel exhaust are comparable to or exceed those reported for spousal smoking, yet neither the EMF or diesel exhaust assessment recommends a Group A classification.

Following are statements contained in the EMF and Diesel Emissions risk assessments and comparative information from the draft ETS risk assessment. *In each of the delineated areas please justify the disparity among the recommended classifications.*

Strength, Consistency and Statistical Significance of Association

EMF: "The association between cancer occurrence and exposure to either EFL or RF files is not strong enough to constitute a proven causal relationship, largely because the relative risks in the published reports have seldom exceeded 3.0 in both childhood residential exposures and in occupational situations."

"The consistently repeated pattern of lymphoma, leukemia, nervous system cancer and lymphoma in childhood studies and the ruling out of several confounding exposure factors in the Savitz et al. (1988) study argue in favor of a causal link between these tumor types in children and exposure to ELF magnetic or electric fields. However, the fact that the odds ratios are small and in many cases not statistically significant indicates that the association may not be strong and therefore argues against a causal relationship."

Diesel Emissions: "Evidence for potential carcinogenicity of diesel exhaust in humans is limited; however, a few recent studies have indicated a small but significant increased risk of lung cancer in occupational exposed workers." A statistically significant risk of 2.6 was reported for miners and heavy equipment operators.

ETS: All studies used in the ETS Draft Risk Assessment have relative risks less than 3.0. EPA's draft calculated a 1.28 relative risk. 17 of 22 studies used in the meta-analysis were not statistically significant.

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Animal Studies

EMF: "Both animal and in vitro studies are needed to discover the relevant exposure factors and their interaction and to gain some understanding of the mechanisms of action."

Diesel Emissions: "Studies employing rats and an adequate experimental design were nearly all positive in demonstrating diesel exhaust-induced increases in tumorigenicity."

ETS: Not included in EPA Risk Assessment.

There are several comments/concerns that were raised during the December 4 & 5, 1990 SAB review panel meeting by panel members. *In order that I might more completely evaluate the comments gleaned from the transcript, please supply me with copies of all written material, such as statements, submitted by members of the SAB Review Panel.* In addition, I would like to raise several of those statements with you and ask questions based upon them. Please note that all quotations are from the transcript of the SAB panel meeting.

Dr. Laties expressed concern over the inclusion of the Hirayama study [called the "flagship study on environmental tobacco smoke" [Transcript, Volume I, page 65] by EPA's Dr. Steven Bayard in his presentation to the SAB panel] in the meta-analysis calculations. Specifically, Dr. Laties commented "I would drop the Hirayama study unless you can defend it against the comments of Dr. Kilpatrick.... If you read this critique you'd be convinced that Hirayama's study should not be cited or not depended upon heavily in this report." This is particularly significant in that Hirayama essentially "drives" the meta-analysis contained in the draft risk assessment. *Please provide an explanation as to why you believe Dr. Kilpatrick's critique is not valid or on the other hand why Dr. Laties' comments are not relevant.*

Another aspect of EPA's guidelines that I have not yet addressed is the role of confounding factors. The draft report did not address this issue. Dr. Benowitz noted, "...there are a number of potential confounders that have been raised and they really should be dealt with explicitly, especially looking at diet and lifestyle factors that really have to be considered and dealt with out front." *On what basis did EPA determine to ignore its guidelines requirement that "[t]he possibility of confounding has been considered and ruled out as explaining the association."* While the confounders may have been dismissed, they certainly were not evaluated. *Do you believe this is appropriate?*

As noted above, the ETS Risk Assessment did not include animal data. From the meeting transcript, it appears it was omitted because it did not support the conclusion EPA staff sought to achieve. Dr. Bayard said almost as much:

> We could have also put in the animal data, too and in fact if we had looked at - - when you look at the guidelines, the guidelines say put in what you know about animals.
>
> We got a lot of comments, we didn't put in any of the animal and smoking data. Whether it was due to condensates or actual inhalation data.
>
> We chose not to because we felt that we wanted to go – in hindsight, or at least according to what I'm hearing it was a mistake but we felt we wanted to go with, quote, the toughest – maybe the toughest data or the epidemiologic data which really had to do with the Class A characterization. [Transcript, Volume II, page 47, my emphasis]

Is such exclusion consistent with EPA policy? What action do you plan to take to insure that this situation does not occur in either the next draft of this risk assessment or future risk assessments on other topics?

During the SAB Executive Committee meeting on April 18, it was stated that there were three separate drafts of the SAB document transmitting the SAB comments on the ETS risk assessment to you. *Please provide me a copy of each of those three drafts as well as the final version transmitted to you.*

A subject of major discussion at the April 18, 1991 SAB Executive Committee meeting was the desire of the panel to have the opportunity to review and comment on the revised risk assessment. In fact, one SAB Executive Committee member urged [and the remainder of the Committee appeared to agree] that the letter of transmittal under discussion should be amended to make more explicit the potential for the committee reviewing the revised document. The need for further review was also made explicit by Chairman Lippmann in his closing comments at the December 4 & 5, 1990 SAB Review Panel Meeting.

> We are persuaded that the evidence exists for – subject to further review of it as it's developed and presented – for considering that ETS does cause lung cancer in non-smokers and that has to be a tentative judgement until we see how you develop the case for it further.
> The case was not, many people felt, was not fully developed in the document that we did review but ... we feel that you should be able to make that case.... So our judgements, of course, are tentative at this point and it depends – and will only be final if we have the opportunity to review a revised document and see the basis for it. [Transcript, Volume II, page 168.]

After reviewing the initial SAB comments presumably you will direct the EPA ORD staff and Indoor Air staff to respond to the SAB comments. *Do you plan to submit the revised document to the SAB for its review as the SAB indicates is desireable, if not necessary? If not, please explain why.*

It is my understanding that EPA currently lists 14 or 15 substances as Class A -- known human carcinogens. For each substance so classified, please provide answers to the following questions:

In considering the epidemiological research, what was the level of relative risk identified for the substance? Was a formal meta-analysis performed?

What was the makeup of these studies in terms of U.S. and foreign?

How many of the substances were classified exclusively on the interpretation of weak association epidemiology studies?

Was there animal research to support the hypothesis?

What confounders were considered and ruled out?

I think it appropriate at this point to consider Dr. Kabat's comments at the SAB review panel meeting in so far as they help illustrate the Agency's apparent inconsistency.

> ... I think classifying ETS as a Class A Carcinogen is maybe a little rash.
>
> In the slide that Steve Bayard showed yesterday it showed the 15 carcinogens that EPA has classed as Class A Carcinogens or known human carcinogens and that included BCME, coke oven emissions, asbestos, vinyl chloride and others and I think that that's not what we're dealing with when we're dealing with ETS. [Transcript, Volume II, page 15-16.]

At the public and press session on April 18 following the SAB Executive Committee meeting, Dr. Lippmann was asked to quantify the risk posed by ETS. He indicated that most people had exposed themselves to greater risk driving to EPA to attend the SAB meeting.

I believe this speaks volumes for the need to review the care or lack thereof that EPA takes in seeing that it adheres to its own guidelines.

Finally, I would like to follow up on the document request contained in my letter dated November 1, 1990. In that letter I requested the following material:

> 1) Such documents as are significant to show all procedures established by EPA, since the 1978 inception of Science Advisory Boards, for identification, evaluation and appointment of members of SAB review panels, including all documents relating to compliance with the requirements of the Federal Advisory Committee Act and all other relevant statutes and regulations in relation to such panels;
>
> 2) All documents relating to the identification, evaluation, and appointment of any proposed or actual members of the ETS review panel, including all documents reflecting the decision-making process within EPA;

3) All documents containing or reflecting communications with any persons or entities inside or outside EPA regarding the actual or potential membership of any person on the ETS review panel;

4) Identification of all individuals within the EPA staff and the SAB who have played a role in the decision-making process with respect to appointments to the ETS review panel, and a description of their role.

I appreciate the material supplied by Dr. Donald Barnes' office in response to this request. I must note that in following up with EPA Congressional Affairs staff as to why there were no documents from the "program office", my staff was informed that the office maintained it had no such documents. I find this particularly interesting since a review of the documents provided by Dr. Barnes indicates that the "program office" recommended a number of the individuals who served on the panel. *Please explain how recommendations such as this could be made without documentation. How did the program office come up with the list of individuals that it apparently recommended to the SAB? What individuals in the program office participated in recommending individuals for such membership?*

As you know, my November 1, 1990 letter expressed interest in whether or not the Federal Advisory Committee Act was being fully complied with. *Please detail any instances in which you have authorized the SAB Executive Committee to meet in non-public session during the past two years on this or any other matter. Please supply copies of any such authorizations.*

While the controversy over Dr. David Burns' membership on the panel has come and gone, I would note for the record that a review of the documents previously supplied by the Agency indicates that a decision not to include Dr. Burns may have been made as early as August of last year. At least, Dr. Burns' name does not appear on some early drafts of the panel membership list. The decision to include him came only after Mr. Axelrad attended an October meeting with Dr. Barnes and anti-smoking activists on the issue of Dr. Burns membership. Dr. Barnes' memo indicates that

> [t]he visitors and Mr. Axelrad, while acknowledging that they can see how the [information concerning Dr. Burns' views] could lead some people to reach a conclusion that Dr. Burns not be asked to serve on the Panel, argue that in the eyes of the public (and Dr. Burns), he was invited to serve via the August 10 memo. Therefore, to reassess the Panel membership at this stage [was] inappropriate and unacceptable. [For The Record Memo, dated October 22; memo attached]

I believe that the referenced August 10 memorandum is within the parameters of my November 1, 1990 request. However, it was not included in the materials that I was provided. I assume this was merely an oversight. *Please provide a copy of this memorandum.*

Your assistance and repsonse to these questions is greatly appreciated. I recognize this letter is lengthy so I have identified those areas where a response is necessary by putting the question or request in italics. Please supply answers to the above questions and requests for documents and information no later than May 31, 1991.

I recognize this request may seem extensive, but I believe the time frame provided should be sufficient in light of the fact that EPA would have had to address or consider most of the issues raised in the drafting of the risk assessment in order to even begin to comply with its own guidelines.

If you have any questions or need any further information, please feel free to contact Mr. Jeff Schlagenhauf of my staff at 225-2815.

With kind regards, I am,

Sincerely,

Thomas J. Bliley, Jr.
Ranking Minority Member,
Subcommittee on Oversight
and Investigations

cc: The Honorable John D. Dingell
Chairman, Subcommittee on Oversight and Investigations

The Honorable F. Henry Habicht, II
Deputy Administrator, Environmental Protection Agency

The Honorable William G. Rosenberg
Assistant Administrator for Air and Radiation
Environmental Protection Agency

Dr. Erich W. Bretthauer
Assistant Administrator for Research and Development
Environmental Protection Agency

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cc: Dr. William H. Farland
Director, Office of Health and Environmental Assessment
Office of Research and Development
Environmental Protection Agency

Dr. Donald Barnes
Executive Director, Science Advisory Board
Environmental Protection Agency

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Section 1.3:

The Economist Criticizes EPA Priorities

This article basically accuses EPA, and William Reilly in particular, of chasing "low-damage, but high-publicity" cases. It criticizes EPA for acting more like a "cancer-prevention than Environmental agency."

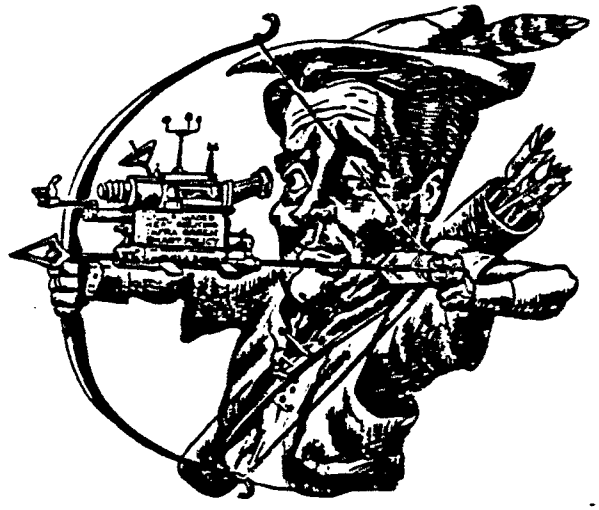
This article supports the allegation that EPA is more interested in a political agenda than an environmental one. If you need more supporting evidence to make this case to interested parties, i.e. journalists or regulators in your market, PMCS can supply you with speakers, articles, videos and brochures.

Clean copies of this document are available in your ETS REFERENCE MANUAL.

LEXINGTON

William Reilly's green precision weapons

AS A paid-up green, William Reilly has not always looked comfortable in the Bush administration. George Bush chose him to run the Environmental Protection Agency (EPA) at a time when he still thought he could co-opt and not alienate the green lobby. Mr Reilly, a veteran conservationist, scored early by helping to push through the first revision of the clean-air law in 13 years. Since then he has been repeatedly outmanoeuvred. He lost battles with the chief of staff, John Sununu, over global warming and wetland preservation. His relations with the budget director, Richard Darman, especially over energy policy, are appalling—Mr Darman calls him a "global rock star". When Congress last year held up legislation to give the EPA cabinet status, wanted by Mr Bush, some people saw the vengeful hand of Mr Darman at work.



Mr Reilly has now embarked on a job which even the cynical Mr Darman should applaud. He is trying to use risk assessment and economics—grubby workman's tools that most greens are too fastidious to touch—to redirect both the EPA's priorities and its approach to regulation.

For all the Reaganite vilification heaped on it, the EPA grew, prospered and regulated mightily in the 1980s. But its efforts were, in the words of a recent scientific report commissioned by Mr Reilly, "inconsistent, unco-ordinated and . . . less effective than they could have been." Too much attention was paid to low-damage but high-publicity cases like oil spills and the famous toxic waste in Love Canal, not enough to habitat loss and global warming. Much of the clean-air act is aimed at acid rain, which a giant official study has concluded is virtually a non-problem.

A telling sign of misplaced priorities, in the eyes of many critics, is the EPA's concentration on health. Something like two-thirds of the agency's staff members work on health-related, not environmental, rules. At times it has behaved more like a cancer-prevention than an environmental agency, making such scientifically dubious decisions as wanting to remove asbestos from school buildings and to ban substances with a microscopically small risk of causing cancer. Only 2-3% of cancers are caused by man-made things anyway.

Does this over-enthusiasm matter? Mr Reilly says yes, for two reasons. One is that environmental protection is too expensive to indulge in without thought of costs and benefits. It will soon take more than 2½% of America's GNP just to comply with existing rules. But the bigger point is that pursuing wrong priorities discredits greenery as a whole—just when it needs friends to defend it from hard-pressed businessmen and rabid deregulators.

Mr Reilly says he wants to stop being reactive. He would rather list the EPA's concerns in order of priority, so that the agency can "take aim before we open fire". Because it has followed public opinion in the past, the EPA has always taken the view that governments are there to stop people having to run risks, however small. Hence, for instance, some of the more onerous provisions of the clean-air act that will produce doubtful benefits at huge cost. The EPA has an enormous education job on its hands, which should be directed at green enthusiasts and aceptics alike.

Identifying priorities is only a start. The next task is to tackle them in the most sensible way. Above all, this means using the economic incentives offered by the market, not regulations to "command and control" things. The Bush administration is proud of the pioneering use of emissions-trading in the clean-air act, which it hopes will cut sulphur-dioxide output for just over half the cost of equivalent regulation. But that did not originate at the EPA. The EPA exists to regulate things, not to see the market do the job for it. Mr Reilly will have to make his own bureaucracy reform itself.

Even the greenest greens are coming to accept market forces (and the value of a growing economy) as a help in cleaning up the environment. Eastern Europe has shown that non-market economies with slow growth can pollute the environment more than most. But, to be really effective, Mr Reilly's enthusiasm needs stretching.

He could start with the federal government itself. The defence and energy departments, impervious to markets, are among the country's biggest polluters. And there is a dreadful stew of federal subsidies and tax breaks (for such things as logging in Alaska, irrigation in California, grazing on federal land in Nevada) that actually subsidise those engaged in making the environment worse. A dose of market reality for get-the-government-off-our-backs westerners could benefit the environment—and save the taxpayer money.

Taxophobia

The best economic incentive to achieve environmental goals is often a tax, for it brings home to consumers the external cost of their consumption without clumsily trying to regulate it away. Yet the government has always found it safer to regulate companies than to tax consumers, and Mr Bush is especially averse to taxes. Though he is too politically cautious to admit it in public, Mr Reilly knows he needs taxes as a weapon in the environmental arsenal, even if they are disguised under another label.

Watch for two tests in the coming months. One is the revision of the clean-water act, which will be ineffective unless it includes taxes or fees on the use of pesticides and fertilisers that leach into rivers. The second will come over fuel-economy standards. Congress and the administration may go for a sharp rise in the average miles per gallon required of car makers, instead of the much more efficient solution of higher petrol taxes.

Mr Reilly may bask in the credibility he has established as Mr Bush's green man, even without being in the cabinet. But his biggest fights are yet to come.

Section 1.4:

Representative Bliley Makes Case on ETS Science
EMF's Handled Differently Than ETS

This first article, written by Representative Bliley, summarizes the main deficiencies in EPA's risk assessment on ETS and its attempt to classify ETS as a Class A Carcinogen.

It is an excellent article for CA people when trying to brief a non-technical person on ETS science. In addition, as the article is written by a US Representative, it clearly supports our claim that the EPA's methods are not globally accepted in US political circles.

I have also attached an article which appeared in the Lancet on EPA's handling of the Electro Magnetic Field issue. As you will see, the evidence on EMF was far "stronger" than ETS. Unlike ETS, however, scientists were quick to point out the speculative nature of the evidence on EMFs.

TOBACCO/SMOKING

ROLL CALL Food and Drug Policy Briefing Thursday, September 12, 1991

Secondhand Smoke Is Not That Risky

Although It's 'Politically Correct' to Be Down on Tobacco Products, the 'Science' Being Used to Link Passive Smoke With Cancer Is Inconsistent, Says Rep. Bliley

By Rep. Tom Bliley

Tobacco is unpopular, and anyone who speaks out on behalf of the product or its users is immediately "tarred and feathered" by legions of zealous tobacco-control advocates.

Nowhere is this more evident than in the debate over environmental tobacco smoke (ETS).

The fundamental question is whether science has proven a health risk to nonsmokers. Anti-smoking advocates would have you believe the scientific debate over the dangers of ETS was settled long ago. They attempt to move their social/political movement forward under the camouflage of "science."

They attack as a tool of the tobacco industry anyone who dares to disagree with their omniscient view of what is good and appropriate for America. When the weakness of their "scientific arguments" are pointed out they revert to an appeal to emotion and with righteous indignation assert the correctness of their regulatory goals.

"Tobacco is bad," they say, "so anything that makes it unpopular, unattractive, and restricts peoples' ability to smoke is good and correct."

Let me be specific. Look at the studies that have been used to weave the issue of "passive smoking." A review of studies on passive smoking was recently published in Consumers' Research. "Of the 30 studies, six reported a statistically significant association (between environmental tobacco smoke and lung cancer) . . . and 24 of the studies reported no statistically significant effect," wrote the authors.

Even attempts to enhance the significance of the individual studies by pooling them for so-called "meta-analysis" are not persuasive. These analyses show relative risks, according to Consumers' Research, of 1.08, or 1.34, or 1.42.

(Relative risk is expressed as a ratio; a risk ratio of 1.0 is, in real terms, a risk of zero.)

Some say even a risk ratio of 1.08 is too high to tolerate, much less a risk of 1.42. In that case, we should all stop drinking milk and impose mandatory exercise requirements on the populace.

If one uses studies only from the US to determine the risk of environmental tobacco smoke, you arrive at a statistically non-significant risk.

One study showed the risk of lung cancer for those drinking pasteurized milk to be 2.1. A lack of physical activity produced a risk of 1.6.

(Cont'd)

Cont'd

There are significant difficulties with the "science" being used to make the case for "passive smoking."

"Confounding variables" is a fancy way of saying other factors may be at work in causing a disease. If confounders are not properly controlled, the study loses reliability.

The "passive smoking" studies have a spotty record, at best, in taking into account the 20 or so "confounding variables" associated with lung cancer. These variables range from nutrition, to genetic predisposition, to ethnicity, to diagnostic criteria. In many Asian studies, exposure to cooking fires and cooking oil vapor seem to be highly significant.

Recent work at EPA demonstrates how manipulation of data can give you different answers to the same question.

The EPA's draft risk assessment on ETS and lung cancer assigned a relative risk of roughly 1.3 to ETS. What is behind that number?

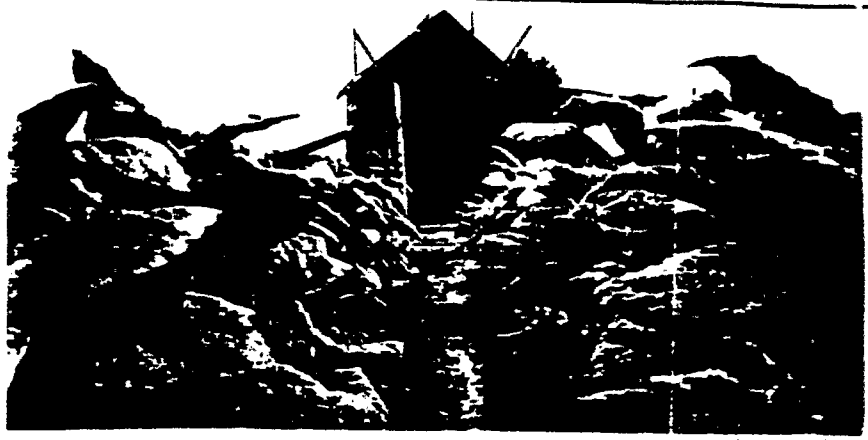
First, if one uses studies only from the United States to determine the risk, you arrive at a statistically non-significant risk. So studies from throughout the world were used to bring the calculation up to 1.3. Included in the international studies was a study done by Japanese researcher Hirayama which has been criticized for serious design flaws. Attempts to obtain the raw data from Hirayama for further analysis are not possible.

Why? The data of this research, published in 1981, have been destroyed. Coincidence or convenience? You decide. If one removes Hirayama from the calculations, the result is dramatically altered.

EPA has Guidelines for Carcinogenic Risk Assessment. These are guidelines to be followed by the Agency in the conduct of risk assessments. Yet in the case of ETS, the guidelines appear to have been applied inconsistently and incompletely.

For instance, the EPA Guidelines require that a risk assessment include not only human epidemiological evidence (fancy terminology for statistical studies usually derived from analyzing questionnaires) but actual animal exposure studies. Guess what? EPA chose not to include the results from animal inhalation studies. Why? The animal data is negative.

Before a causal interpretation is drawn from epidemiological data, it is generally a recognized principle that risk ratios must exceed 2 or 3. Part of the reason is that lower ratios can often be achieved merely on the basis of chance, bias, confounding, or, in the case of ETS, misclassification. In such cases, it is inappropriate under EPA's Guidelines to make a causal interpretation.



"The fundamental question is whether science has proven a health risk to nonsmokers," writes Rep. Bliley. Explaining that data from risk assessment studies can be manipulated, he argues, "The issue is...a desire by anti-tobacco activists to eliminate tobacco from the landscape." Above, a tobacco field north of Reidsville, N.C.

Misclassification is the term used to refer to individuals who are smokers but say they aren't. EPA's calculated risk is low enough that, according to some studies, it can be explained entirely on the basis of misclassification or the common lifestyle factors among spouses who live with smokers, such as diet, exercise, or alcohol consumption.

Some of the most illustrative evidence of what is going on here comes from the words of individuals involved in the process at EPA. When the EPA Science Advisory Board (SAB) Executive Committee reported on its review of EPA's draft risk assessment it noted that it had "difficulty in applying the Guidelines ... as they are currently formulated to this complex and variable mixture."

EPA chose not to include the results from animal inhalation studies in its risk assessment. Why? The animal data is negative.

The SAB report said "if Guidelines for Carcinogenic Risk Assessment can be used to cast doubt on a finding that the inhalation of tobacco smoke by humans causes an increased risk of lung cancer, the situation suggests a need to revise the Guidelines."

This prompted one member of the SAB Executive Committee to note that it sounded a little like they were saying "if the data doesn't fit the guidelines, the guidelines should be changed."

Following that meeting Dr. Morton Lippmann, who chaired EPA's review panel, was asked to quantify the risk of exposure to environmental tobacco smoke. He indicated that most people had exposed themselves to greater risk driving across town in Washington traffic to EPA to attend the meeting. And the very next day when there was no press coverage of the SAB Executive Committee meeting, Dr. Lippmann acknowledged that if the EPA guidelines were applied as written, or in his words "rigidly," there was "no clear mechanistic basis for calling [ETS] carcinogenic."

Dr. Jonathan Samet, another member of the EPA review panel, published an article in the Aug. 7, 1991 Journal of the American Medical Association [JAMA]. While Dr. Samet believes ETS is a carcinogen, he finally recognizes the numerous problems and uncertainties with the ETS epidemiological studies. Ironically, these criticisms would preclude a known human carcinogen classification for ETS under EPA's Guidelines.

He states that "because of the methodologic difficulties of assessing lifetime exposure to ETS and precisely describing risks that are not substantially elevated, these uncertainties in assessing the lung cancer risk of ETS may never be fully resolved though they remain a subject of research."

Despite the equivocal nature of the science, Dr. Samet very clearly articulated the "politically correct science" of ETS when he went on to say, "in the case of ETS it would be unfortunate if potentially irresolvable scientific uncertainties thwarted control."

The issue is control. It is a desire by anti-tobacco activists to eliminate tobacco from the landscape. Clearly, they have no interest in allowing objective scientific evidence to get in the way of achieving that goal. To do so would be politically incorrect.

Rep. Tom Bliley (R-Va) is ranking minority member of the oversight and investigations subcommittee of the Energy and Commerce Committee.

reduction in child smokers after introducing its advertising ban in 1975. As the Coronary Prevention Group sets out in the revised text of its Case Against Tobacco Advertising, which will be published next week, non-binding voluntary agreements with the tobacco industry may control certain elements of advertising style but do little to reduce the amount or effectiveness of advertising.

The news from Brussels, where officials met again last week, was that Germany was beginning to wobble. Only one of the four states opposing the ban has to bend to allow the new controls to come into force. Voting is based on population. There are 76 votes in all, and 54 are needed to get it through. The EC health ministers, who discussed the draft at their spring get-together, meet again in November to ratify it. Britain is probably the most hardline opponent of the move. The presidency at present is held by the Dutch, but if the decision is delayed beyond November then Portugal, which has already banned advertising at home, will be in the chair. Meanwhile a new organisation, Doctors for Tobacco Law, has emerged with the backing of 26 medical organisations including the Royal Colleges. It is already claiming to be the largest medical coalition in the UK. One of its leading members, Prof John Moxham of King's College Hospital, London, declared: "The cure for tobacco disease cannot be found in doctors' surgeries—it lies in MPs' surgeries". The coalition is sending MPs the grisly details of the cancer and coronary deaths caused by tobacco.

Malcolm Dean

Round the World

USA: Problems with power lines

Scientists at the Environmental Protection Agency who are reviewing the health effects of electromagnetic fields (EMF) from power lines and other sources at first wanted to call the radiation a "probable carcinogen". Overruled by their superiors, they toned it down in the published draft to a "possible but not proven cause of cancer in people". Currently, non-government scientists on a panel of the EPA's science advisory board advise even greater caution. They believe the final report should say: "There is limited information on the potential carcinogenicity of EMFs in humans".

Given the high standing within the EPA of its science advisory board, the authors are bound to take this recommendation seriously when they rewrite the draft. Such a conclusion should come close to meeting the objections of D. Allan Bromley, President Bush's science adviser. He has strongly opposed even the suggestion of a link between EMF and cancer (*Lancet* 1991; 337: 544). Robert Adair, his fellow physicist at Yale University, claims that "An examination of the physical interaction of [EMF] with the body shows that such interactions are too weak to have a significant effect on human biology at the cell level" (*Physical Review A*, Jan 15, 1991, p 1039).

That judgment has made an impression on epidemiologist Genevieve Matanoski, of Johns Hopkins University, chair of the EPA panel which is reviewing the 1990 draft of the report, called *Evaluation of the Potential Carcinogenicity of Electromagnetic Fields*. Dr Matanoski, the principal author of an EMF study that found unexpectedly high cancer rates among linemen for the New York Telephone Co, says that the authors of the EPA report need to come to grips with Dr Adair's objections. "The theory of physics", she told me, "shows none of this can happen". But the panel also said that cancer incidence could be affected by an agent that does not produce mutations, citing as examples the influence of hormonal imbalance and nutrition on cancer promotion.

The Matanoski panel also had reservations about the evidence on which reports of links between EMF and cancer are based. Here the principal objection was to the absence of quantified exposures to EMF. Another drawback was said to be the "limited understanding of possible biological mechanisms" that could cause cancer. Still, said the panel, "the evidence cannot be dismissed". The whole question of EMF effects, it said "is important and exceptionally challenging".

It could take at least a year for the EPA to rewrite and publish this document. Aside from wanting to make sure the science is accurately presented and interpreted, it is clear that President Bush's advisers and the science advisory board panel also hope to avoid any language that would, as the Matanoski panel expressed it, "reinforce the skewed and somewhat sensationalized picture presented to the public in recent years by the news media".

J. B. Sibbison

Italy: An end to the fun and games?

Medical congresses have widely served to spread scientific information while at the same time "rewarding" loyal physicians for their attachment to a given pharmaceutical company. These gifts to physicians may be extremely varied and may include trips to exotic places for the whole family, cruises after a few lectures, gala dinners, evenings on the town, and expensive presents. The whole process comes under the broad umbrella of "scientific information" needed to keep physicians abreast of the progress of medicine.

The Italian Ministry of Health has now decided to put a stop to these extravaganzas, presumably with the agreement of the Association of the Pharmaceutical Industry (Farmindustria), whose members are alarmed by the escalating costs of scientific meetings. On Dec 12, 1990, the Ministry issued a decree, which became effective in March, 1991, that scientific congresses organised in Italy or abroad by pharmaceutical companies based in Italy or financially supported by them, even indirectly, must be free from advertising and must aim only at the improvement of knowledge in medical disciplines. When a company wishes to organise a scientific meeting it must apply to the Ministry of Health at least 60 days in advance, giving information about where the meeting will take place, the type of participants, the topic of the meeting, the speakers' qualifications, and an undertaking to avoid any form of advertising. In addition the company must give a detailed budget, which should not include any expenses for travel and lodging for the participants, except the speakers and some poorly defined "qualified professionals of the discipline of the meeting, useful for the success of the meeting". Advertising, distribution of free samples, and displays of promotional exhibits during the meeting are forbidden. A decree in preparation will probably allow firms to support meetings without requiring any authorisation if

Section 1.5:

PMCS Briefing Paper on ETS and EPA

This short briefing paper on EPA summarizes opinions expressed by leading European scientists and official European bodies which fly in the face of EPA's conclusions. It also points out some of the deficiencies in EPA's risk assessment.

This document must still be revised. A final copy will be forwarded to you. In the meantime, it can be used to familiarize yourself with the generalities of EPA's review on ETS.

THE U.S. EPA'S DRAFT ETS RISK ASSESSMENT

INTRODUCTION

When the Environmental Protection Agency (EPA) first released its draft risk assessment on environmental tobacco smoke (ETS) for public comment in June 1990, it created a significant scientific controversy.

The draft's conclusions, that ETS was a Group A or "known human" carcinogen and that 3,800 Americans die every year from lung cancer caused by exposure to ETS were strongly disputed by many scientists.

The vast majority of scientists who filed comments with the EPA on its draft report disagreed with the agency's conclusions, and even a member of the EPA's own Science Advisory Board stated publicly that classifying ETS as a known human carcinogen may be "rash".

And yet, the EPA are expected to confirm their conclusions in their final report. And already the figure of 3,800 American deaths a year has become an accepted 'scientific fact'. Amid such controversy, it is worth taking a closer look at the EPA's draft risk assessment on ETS and claimed health effects.

THE DRAFT REPORT

The draft report was based on 24 published epidemiologic studies on lung cancer incidence among non-smokers married to smokers. It is the first risk assessment ever conducted by the EPA based entirely on epidemiologic evidence.

Of the 24 published studies, 19 report no statistically significant increased risk, including the nine US studies. The remaining five studies report risk ratios that are weak at best, all below 3.0 and well within the range epidemiologists consider difficult to interpret because of problems inherent in study design and conduct. These five studies were also conducted in countries outside the US and, according to some members of the scientific community, improperly controlled. The studies all suffer from a number of serious flaws, including:

Poor exposure classification

Exposure is based on reports of spousal smoking. There are no real measures of the actual existence or degree of non-smoker exposure.

Confounding Factors

Research indicates that smokers, and their spouses, tend therefore to have poorer diets, a reported contributor to lung cancer. Other factors include alcohol consumption, occupational exposures, exercise, genetic predisposition and socio-economic status. None of these "confounding factors" were well considered in these studies.

FAILURE TO FOLLOW EPA GUIDELINES

The draft report is solely based on epidemiology and involves all of the most difficult issues inherent in epidemiology - weak statistical associations, indirect and unreliable measures of exposure to ETS, extremely low levels of exposure and numerous possible sources of bias and confounding factors.

And yet, the EPA did not follow the recommendations of a panel of distinguished epidemiologists as to the limitations of using such data in making risk assessments. This panel was convened at the EPA's request to issue guidelines for the assessment of carcinogens based on such data.

The panel's recommendations, outlined in a 1986 EPA report, contained five criteria to assure that the data were adequate to reach conclusions, but none of these criteria were apparently applied to the EPA's draft ETS risk assessment.

Apparently, the agency is also applying its carcinogen classification guidelines inconsistently. As the attached chart shows, the EPA concluded in its recent draft risk assessment on exposure to electromagnetic fields (EMF) that such exposure could not be viewed as causing cancer. Yet the data base on EMF exposure was stronger in some respects than that for ETS. → (See comparison in Appendix II)

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THE REVIEW PROCESS

The draft report was reviewed at a meeting of the EPA's Science Advisory Board (SAB) on December 3 and 4, 1990.

The panel members were provided with copies of the draft as well as copies of the extensive scientific comments submitted to the agency. During the public presentations it became clear that a number of panel members were unfamiliar with the issues raised in the public comments and some even stated on record that they had not looked at the scientific comments.

The great majority of scientists who filed comments with the EPA were severely critical of the agency's conclusion. The SAB's own consensus was reached despite serious doubts expressed by many panel members about the adequacy of the data.

At the end of the review, the SAB's Chairman stated that, while the EPA had not "made the case" for concluding that ETS is a "known human" carcinogen, the consensus of the committee agreed with the EPA's conclusion.

The SAB's recommendations - that the EPA rewrite virtually everything in the draft report except the conclusions - have now gone back to the EPA.

The EPA has said that, in revising its risk assessment, it will consider studies published since the initial draft was completed. However, the most recent ETS-lung cancer study,† a large case control study of Chinese women, was never mentioned during the SAB's review, despite the fact that one of the co-authors was a member of the panel, nor was it provided for inclusion in the risk assessment's calculations.

The study reported no association between spousal smoking and lung cancer, in fact it reported a statistically significant inverse relationship.

When this study and two others omitted by the EPA are added to the EPA's meta-analysis* the results do not show that spousal smoking is statistically associated with the risk of lung cancer in non-smokers.

† Wu - Williams et al

* See Footnote: Meta-Analysis

CONCLUSION

A careful scientific review of the literature reveals that the EPA draft documents on ETS are an uncritical condensation of selectively chosen studies, subjected to a series of highly speculative adjustments seemingly to reach a "predetermined outcome".

There is a considerable body of scientific thought in Europe, as well as in the US, that places no credence in the EPA's conclusion. And there appears to be no way in which to apply the agency's own current carcinogen classification guidelines on the available data on ETS and reach the conclusion that the EPA seems to want to reach.

As far as the EPA's draft workplace policy guide is concerned, many of the same scientific concerns apply. Equally, since the agency's analysis concerned only ETS at home and not data on ETS in the workplace, workplace guidelines from the EPA are clearly inappropriate.

APPENDIX I

A EUROPEAN PERSPECTIVE

The clear majority of scientific comments filed with the EPA on the draft report challenge the agency's conclusions. Among these comments are a considerable number of contributions from eminent European scientists:

- Professor B. Schneider, of the Institute of Biometry of the medical school in Hanover, Germany, reanalysed the data employed by the authors of the ETS epidemiologic studies and concluded that: "a valid statistical analysis does not reveal any significant association between ETS and any health risks".

- Petr Skrabanek, Senior Lecturer on Community Health at Trinity College, Dublin, questioned EPA's heavy reliance on its meta-analysis of epidemiologic studies (especially by Hirayama) carried out on Asian women: "Such women are unsuitable for studying the effects of ETS, given evidence of strong confounding factors and because even active smoking in these women has been only weakly associated with lung cancer and the majority of lung cancer cases are non-smokers". Further, he detected "serious unresolved problems of biological plausibility" in the EPA draft.

- UK statistician Peter Lee, to whose work the EPA draft made numerous references, provided an exhaustive analysis of every epidemiologic study conducted with respect to ETS exposure and lung cancer. The key flaws he detected in the EPA draft, which in his view made it "unacceptable", were its "overestimation of epidemiological in relation to dosimetric evidence"*, its "omission of relevant data and inclusion of inappropriate data in the meta-analysis of the epidemiological evidence", its "errors in adjustments for bias due to misclassification of smoking habits" and its "errors in applying the adjusted meta-analysis risk estimates".

- R.C.Brown of the Medical Research Council Toxicology Unit in the UK cautioned that the acceptance of the EPA draft's unfounded conclusions could lead to the misattribution to ETS exposure of many lung cancer cases that are in fact due to as yet unidentified causes.

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* See Footnote: Dosimetric Approach

- Professor Ragnar Rylander of the Department of Environmental Hygiene at the University of Gothenburg, Sweden pointed out that the average exposure to tobacco smoke constituents in ETS exposed individuals is exceedingly low, providing grounds for scepticism about a causal relationship with respect to lung cancer. He offered the judgement that: "the arguments for biological plausibility in the {EPA draft} unfortunately do not reflect a critical scientific evaluation of the critical toxicological and epidemiological concepts involved".

- Professor Guy Crepat, head of the Applied Biology Dept at the University of Burgundy, France, disputed the EPA draft's reliance on an assumed linear relation between the claimed cancer risk from ETS and the level of cotinine (a metabolite of nicotine) in the body fluids of non-smokers, and argued that such reliance leads inevitably to an overestimation of risk.

- UK pathologist F.J.C.Roe, formerly head of The Department of Experimental Pathology at the London Institute of Cancer Research, took the EPA draft to task for its "wholly unscientific and wholly invalid" use of meta-analysis and expressed the view that "the only safe conclusion that can be based on the available evidence is that it remains unclear whether there is any lung cancer risk from exposure to other people's tobacco smoke and if there is any such risk there is absolutely no reliable way to quantify it".

FOOTNOTES:

META-ANALYSIS

The controversial statistical tool of meta-analysis combines a number of studies to produce a single estimate of relative risk. It is generally used when studies standing alone lack a sufficient number of cases to justify any association. The EPA draft makes no effort to distinguish between US and non-US studies. The meta-analysis of the US studies considered in the EPA draft yields a result that is not statistically significant and therefore provides no basis for any prediction of risk.

DOSIMETRIC APPROACH

The EPA's standard method of risk assessment is the dosimetric approach. This method extrapolates to low exposures from effects reported in higher exposures. Using this approach the risk estimate for ETS is hundreds of times lower than the estimate from the EPA's review of the epidemiologic studies.

APPENDIX II

STATE OF THE SCIENCE IN EUROPE

International and National health agencies throughout Europe have come to somewhat different conclusions on ETS than the EPA. Their conclusions have been more considered:

- The Committee of the Health Council of the Netherlands recently evaluated all the major articles and studies on ETS prior to June 1990 at the request of the Dutch government. The report concluded: "To evaluate the effect of exposure to ETS one has to rely mainly on the results of epidemiological research carried out among non-smokers. This kind of research is beset by methodological problems which may distort the outcome."

  "The Committee would emphasise that the apparent increase in lung cancer risk could be partly due to flaws in the design of the epidemiological studies. As it is not known to what extent the results of the several studies are distorted, the Committee is of the opinion that quantitative estimation of the additional lung cancer risk of non-smokers exposed to tobacco smoke is not possible at present".

→ Social life !

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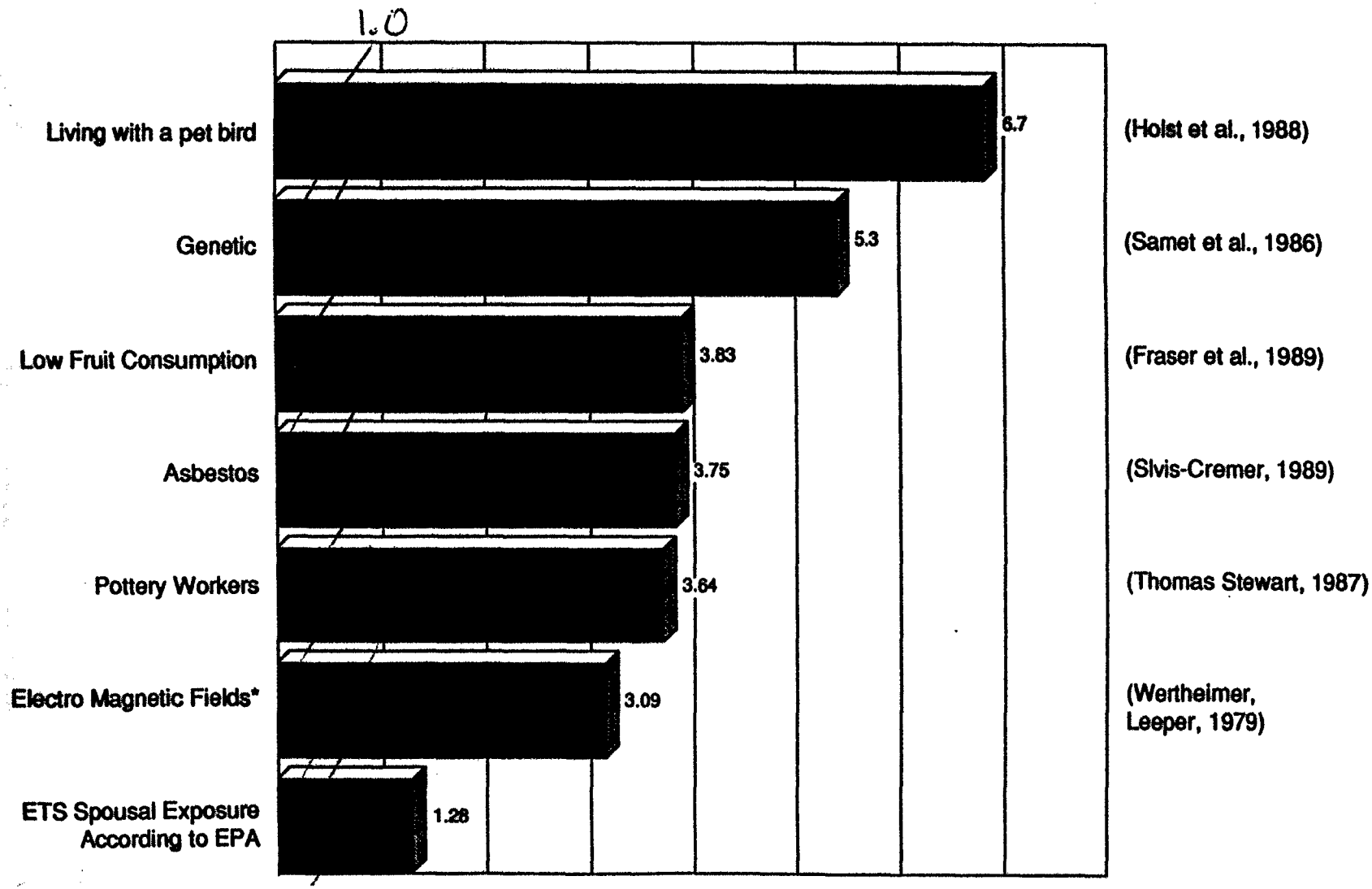
Lung Cancer Relative Risks



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EMF - Electromagnetic Fields

"The association between cancer occurrence and exposure to either EFL or RF fields is not strong enough to constitute a proven causal relationship largely because the relative risks in the published reports have seldom exceeded 3.0 on both childhood residential exposures and in occupational situations."

"Both animal and in vitro studies are needed to discover the relevant exposure factors in their interaction and to gain some understanding of the mechanisms of action."

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ETS - Environmental Tobacco Smoke

All studies used in the meta-analysis calculation have relative risks less than 3.0. The EPA calculated the relative risk for ETS (via meta-analysis) to be 1.28.

Animal studies attempting to elicit lung cancer as a result of ETS exposure have failed.

Section 1.6:

ETS: Rush to Judgement - A PM Brochure

This pamphlet is still being adapted for European audiences. The references to baseball, certain studies, and quotes will be changed to achieve a more "European slant".

Once the final changes have been made, a copy will be forwarded to you for translation into your local language(s). I will send you instructions to have the translations legally cleared and will be available to assure the quickest possible clearance procedure.

Once the translations have been cleared and the pamphlets printed, you will be free to use the brochure as you see fit. I would recommend, however, that the brochures be used to generate interest before the EPA's official announcement, now expected in late February or early March 1992.

Once the media interest has been generated, you can invite journalists to a full background briefing. PMCS can help supply you with specially adapted press briefing programs; our resources include Tom Borelli, Science & Technology, London visits through C&B, and Tony Andrade.

PHILIP MORRIS INTERNATIONAL INC. INTER-OFFICE CORRESPONDENCE

800 WESTCHESTER AVENUE, RYE BROOK, NEW YORK 10573-1301

TO: Distribution

DATE: October 16, 1991

FROM: Matthew N. Winokur

SUBJECT: New ETS Brochure

Attached is a cleared, pre-publication copy of a new brochure on ETS. I believe you will find both the brochure as a whole and the references within it useful in dealing with the ETS debate. I suspect that some of you will find it most useful to create your own variations of this brochure adapting certain parts to local conditions; including inserting your own company identification. The baseball analogy used to explain meta-analysis could easily be adapted to football. As the use of this analogy indicates, this brochure explains a complex subject in down to earth terms. It may be particularly useful in responding to the EPA process, although much of the information on ETS alone could be used as a free standing brochure.

Of course, any variations on this brochure must be cleared by legal.

MNW/vfr
pmi1016.doc

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↳ EPA invol new study → Al
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* Send English update to markets They will translate. I must provide instruction to legal Clearance!

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ENVIRONMENTAL TOBACCO SMOKE:

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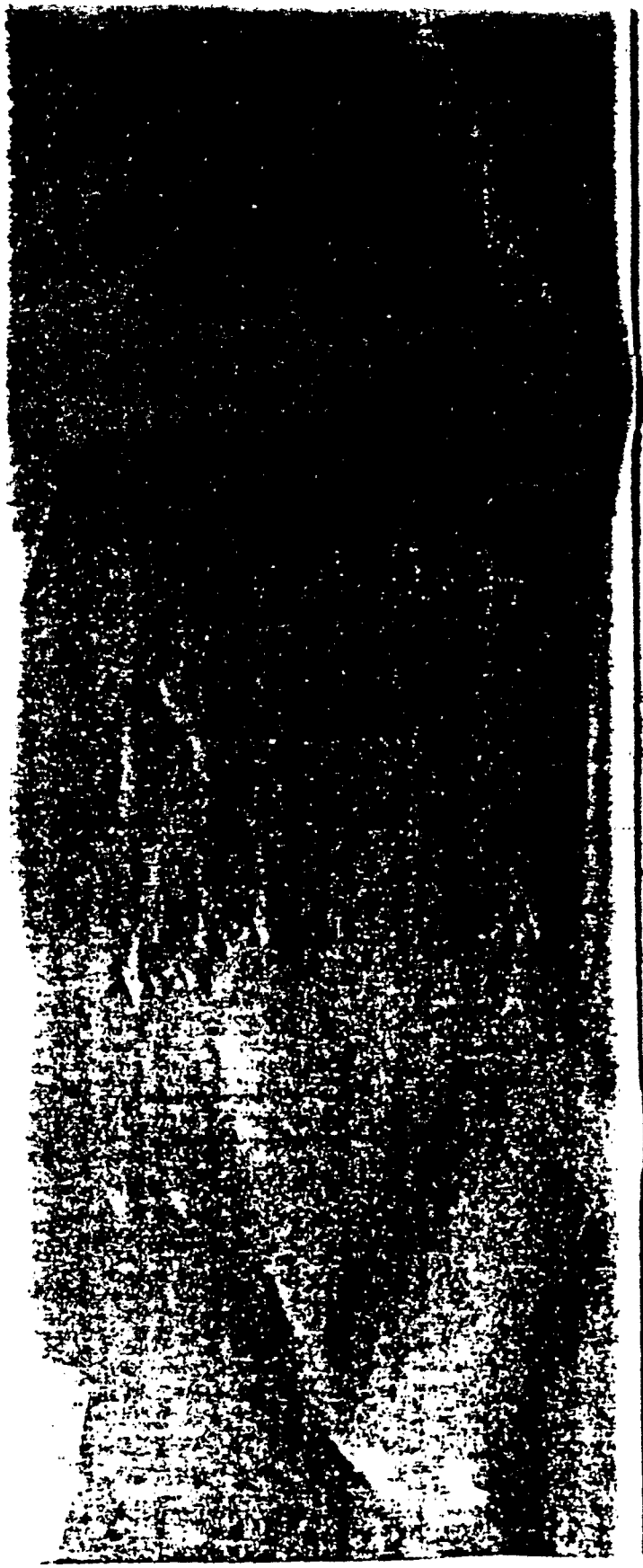

ETS AND THE EPA— BEHIND THE HEADLINES

THERE IS A GROWING BODY of scientific opinion that there is no statistically significant increase in the potential risk of lung cancer in nonsmokers exposed to environmental tobacco smoke (ETS). However, a draft report based on spousal smoking released last winter by the Environmental Protection Agency (EPA) claimed ETS—often referred to in the press as "secondhand smoke"—is a cause of lung cancer in nonsmokers.

Although the EPA announcement made headlines, few members of the general public are aware that a number of highly reputable scientists have disputed the EPA's claims and criticized the methods by which the agency arrived at its risk assessment. (See "What the Experts Are Saying," page 6.)

In its draft report, the EPA claimed that ETS carries a relative risk for lung

cancer in nonsmokers of 1.28 (a relative risk of "1.00" means there is no statistical risk). To put this into perspective, one study has reported the relative risk of developing lung cancer associated with drinking green tea to be 2.7, and another concluded the relative lung cancer risk reported for keeping birds as pets is 6.0! Epidemiologists consider relative risks of less than 2 to be "weak." (See "A Word About Risk," page 8.)

THE EPA HAD TO WORK HARD TO COME UP WITH ANY INCREASED RISK AT ALL.

But even a relative risk of 1.28 for ETS is highly questionable when one considers how hard the EPA had to work to come up with any increased risk at all. For example:

- Eighteen of the 23 studies considered by the EPA report no statistically significant association between ETS and lung cancer in nonsmokers.
- The five studies that do purport to show a significant increased relative risk were all conducted on non-U.S. populations, where dietary and other lifestyle habits may have affected the results.
- Some of the studies that claimed to demonstrate increased relative risk were small; one study had only six subjects. Men, in particular, were largely underrepresented in the five foreign studies that claimed to find increased relative risk. One study had only two men.
- One of the largest studies done in the world was released only last December and reported that nonsmoking spouses of smokers actually had *less* relative risk of developing cancer than nonsmokers married to other nonsmokers. One of the authors of this study was a member of the Science Advisory Board evaluating the EPA's draft report. This member never mentioned his own study during the entire EPA review.
- Two additional Asian studies released around the same time also reported no statistically significant risk for lung cancer in nonsmoking women married to smokers. All three of the new Asian studies adjusted for cultural differences, and found that Asian cooking and heating techniques posed an increased risk for the development of lung cancer among nonsmoking women, independent of reported ETS exposures.
- The EPA originally excluded one of the largest U.S. studies ever done on ETS, conducted at Yale University by Dr. Luis Varela. A report on that study was published in *The New England Journal of Medicine*. The study of 191 subjects found no statistically significant link between ETS and lung cancer in either nonsmoking spouses or coworkers.

ONE OF THE LARGEST U.S. STUDIES EVER DONE ON ETS FOUND NO STATISTICALLY SIGNIFICANT LINK BETWEEN ETS AND LUNG CANCER IN SPOUSES.

- Although the EPA eventually agreed to use data from the *The New England Journal of Medicine* article, the EPA report's conclusions are still being distorted by the inclusion of a much-criticized, 10-year-

old Japanese study—the Hirayama study. The EPA describes Hirayama as its "flagship" study. Yet Dr. Victor G. Laties, Professor of Toxicology at the University of Rochester's Environmental Health Science Center and a member of the Science Advisory Board reviewing the EPA draft report, said, "I would drop the Hirayama study." And Dr. William J. Butler of Failure Analysis Associates Inc. criticized the report for relying on Hirayama, which he said contained "very substantial flaws ... [that] have not been answered." When asked to provide the raw data from his study for independent examination, Dr. Hirayama delayed for more than a year and ultimately said he could not produce his raw data because they had been destroyed.

IN ITS RUSH TO BRAND ETS A "KNOWN CARCINOGEN," THE EPA IGNORED MANY CRITERIA IN ITS OWN GUIDELINES.

■ In 1986, the EPA issued internal guidelines for evaluating carcinogenic risk. In its rush to brand ETS a "known carcinogen," the EPA ignored many criteria in its own guidelines.

■ Two studies that came out while the EPA was preparing its draft report were ignored by the agency; neither showed a statistically significant relationship between ETS and lung cancer in nonsmokers.

■ The EPA released workplace policy guidelines for dealing with ETS at the same time it released its draft report—*without* waiting for comment from a panel of impartial scientists. The EPA was all set to issue guidelines on dealing with the "problem" of ETS before the EPA's own advisory board had even had a chance to determine if a problem did indeed exist.

■ The EPA has treated other environmental substances differently. Recently, the agency investigated electromagnetic fields (EMFs) and diesel emissions as possible carcinogens. Although the data against both were arguably more complete than the data on ETS, the EPA refused to classify EMFs, and would only label diesel emissions a "probable" carcinogen.

■ To get the results it wanted from the data it selected, the EPA employed a process called "meta-analysis," an "apples-and-oranges" model that many scientists find questionable. The results are based on small samples and show weak correlations. (See "Baseball and Meta-Analysis," page 9.)

META-ANALYSIS IS AN "APPLES-AND-ORANGES" MODEL THAT MANY SCIENTISTS FIND QUESTIONABLE.

When only the studies conducted in the United States are subjected to this analysis, and the overseas studies are dropped, the relative risk for ETS is lower than the 1.28 estimated by the EPA—that is, there is no statistically significant increased risk.

■ When scientists outside the EPA assessed the risk of developing cancer from exposure to EMFs, a relative risk of 2.0 was established. Why did the EPA use meta-analysis for ETS, but not for EMFs?

WHAT THE EXPERTS ARE SAYING

"I looked at [the draft report] ... and thought to myself, How would I have graded it?... With all due respect to all the work put in, I would not be able to give it a passing grade."

Dr. Paul Switzer
PROFESSOR
DEPARTMENT OF STATISTICS
STANFORD UNIVERSITY

"One has to acknowledge the fact that one of the largest studies, the Varela and Janerich study, which was apparently more thorough than most of the studies, fails to find any positive association for spousal smoking or workplace exposure.... I think classifying ETS as a Class A carcinogen is maybe a little rash."

Dr. Geoffrey Kabat
(EPA Science Advisory Board member)
SENIOR EPIDEMIOLOGIST
AMERICAN HEALTH FOUNDATION

"The totality of data on ETS and lung cancer does not support the claim made in the draft EPA report that ETS is responsible for an increased incidence of lung cancer in the United States.... There is no scientifically valid basis for conducting a risk assessment on ETS or classifying ETS as a known carcinogen or even probable human carcinogen."

Dr. W. Gary Flamm
CONSULTANT
SCIENCE REGULATORY
SERVICES INTERNATIONAL

"It is apparent that this collection of studies lacks precision ... and that the studies are both inconsistent and very close to observing zero associations."

Dr. Maurice E. LeVois
CONSULTANT
ENVIRONMENTAL HEALTH SERVICES

"The studies ... that are being considered here have a very low likelihood of even finding anything."

Dr. Jan A. J. Stolwijk
(EPA Science Advisory Board member)
VICE CHAIRMAN
DEPARTMENT OF EPIDEMIOLOGY
YALE UNIVERSITY SCHOOL
OF MEDICINE

Political ⇒ Borell. Test

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A WORD ABOUT RISK

DID YOU KNOW THAT AN epidemiologic study has reported that the relative risk of developing lung cancer if you are a construction worker is 1.4, which is higher than the overall relative risk for lung cancer the EPA assigned ETS?

Other substances and activities that have been identified as possible risk factors for lung cancer include car exhaust (1.5), physical inactivity (1.6), and keeping birds as pets (6.0); all report higher relative risks in at least some studies than the EPA claims for ETS.

The fact is, statistical analysis is making it possible for epidemiologists to identify more and more possible risk factors for certain diseases. Virtually every activity can be statistically associated with disease—if only you analyze it exhaustively.

VIRTUALLY EVERY ACTIVITY CAN BE STATISTICALLY ASSOCIATED WITH DISEASE.

An editorial writer for *The New England Journal of Medicine* advocates putting such weak relative risks into perspective. A recent editorial states that while there is no question that epidemiologic studies are "of growing interest.... it is important, however, to remember the pitfalls in interpreting them and to be cautious in advising patients on the basis of single or conflicting studies.

"This is particularly true of studies that purport to show only weak associations between exposures and disease."

A relative risk of less than 2.00 is generally considered "weak" and, as noted previously, the EPA has assigned ETS a relative risk of only 1.28. Clearly, as the tools of computer science become more available, and our ability to perform statistical computations increases, we must be able to identify legitimate significant risks and distinguish them from statistical anomalies.

Tennis ~~BASEBALL~~ AND "META-ANALYSIS"

THE EPA ARRIVED AT ITS RISK assessment for ETS by using a process known as "meta-analysis." This means that instead of evaluating each study individually, the EPA combined data from all 23 of the studies under review and came up with a sort of weighted average.

Meta-analysis would enable a ~~base~~ foot ball team to win the World ~~Series~~ Cup, even if it lost four out of the first five games.

If the team won the first game by 5-0, and then lost the following four by 1-0, meta-analysis would dictate that the team winning the first game had won the ~~series~~ Cup.

By using meta-analysis, a researcher can lump together a number of studies with inconclusive or marginal results and manufacture a finding that, "overall," the studies were statistically significant. It ignores the very differences that the scientific method is designed to control.

Without this process, the EPA would not have been able to claim that the data against ETS were significant.

Dr. Joseph Fleiss, of the Columbia University School of Public Health, criticized the EPA for resorting to meta-analysis in its draft report on ETS.

META-ANALYSIS IGNORES THE VERY DIFFERENCES THAT THE SCIENTIFIC METHOD IS DESIGNED TO CONTROL.

"Biases due to confounding, or due to misclassification," Dr. Fleiss said, "will not average out when we accumulate evidence across different studies. They will reinforce one another."

In other words, whether in ~~baseball~~ Tennis or science, the outcome depends a great deal on who is keeping score.

SICK BUILDING SYNDROME

IN FOCUSING ALL OF ITS ATTENtion on environmental tobacco smoke, the EPA ignores the very real problem of indoor air pollution and sick building syndrome (SBS).

SBS occurs when inadequate ventilation and indoor pollutants combine to affect adversely the health of a building's occupants. Individuals who work in buildings afflicted with SBS often complain of headaches, fatigue, nausea, dizziness, and recurring flu-like symptoms.

According to indoor air quality experts, ETS is not a major cause of complaints in SBS. One such expert, chemist Gray Robertson, president of Healthy Buildings International Inc., examined 125 buildings suffering from SBS and found that ETS was not a significant factor in 96 percent of them. Thirty-one percent of the buildings Robertson examined, however, had problems stemming from widespread allergenic fungi breeding in air-conditioning systems.

Other indoor air pollutants that can contribute to SBS include building materials and furnishings, office equipment, supplies and cleaning products, mold spores, allergens, and infectious agents.

One of the most publicized serious cases of building-related illness occurred in Philadelphia in 1976, when 29 American Legion conventioneers died of Legionnaires' Disease as a result of exposure to an infectious agent breeding in their hotel's air-conditioning system.

Ironically, the EPA's own offices in Washington, D.C., suffered from a particularly bad case of SBS. *The Washington Post* reported that some EPA employees resorted to wearing gas masks to work. The newspaper story quoted an indoor air quality expert, hired by the EPA, who estimated that 10 to 20 percent of the agency's work force had become ill as a result of phenylcyclohexane (4-PC) and other indoor air pollutants present at the agency's Washington office complex.

INDOOR AIR QUALITY EXPERTS SAY ETS DOES NOT CONTRIBUTE SIGNIFICANTLY TO SBS.

ETS is certainly not a factor in the

Was banned at the time it happened

EPA's indoor air pollution problem: Smoking is banned in all areas of the EPA's headquarters.

Motive of EPA

Nonsmokers who dislike smoking can be accommodated reasonably. Accommodation also means that clean and easily accessible smoking areas are provided for the more than 50 million Americans who choose to smoke.

THE RATIONAL ALTERNATIVE

THE CLAIM THAT ETS IS A CAUSE of disease in nonsmokers is not justified by scientific data. Moreover, studies indicate that under normal conditions, ETS is not a significant contributor to indoor air quality. Nevertheless, there are people who are simply annoyed by cigarette smoke and these people deserve to be accommodated.

Providing a smoke-free public environment for those who desire one does not mean that all public smoking must be banned. One-third of the adult public chooses to smoke, and the rights and preferences of this group are just as worthy of respect as those of nonsmokers.

Unlike many claims against ETS, which are not conclusively supported by the available scientific data, the fact that some people do not ~~want to be exposed to ETS~~ like smoke is a valid issue, one that can and should be addressed. But it is an issue that can be solved through accommodation, ~~and~~ common sense, and courtesy. Solutions that address the rights of one group at the expense of another are inappropriate for democratic societies. unnecessary and doomed to failure. Policies based on accommodating both smokers and nonsmokers, on the other hand, will have more support and lead to greater harmony.

Political aspects

Summarize & ask questions

EPA raises more questions than answers

Section 2.1:

Executive Summary of the Health Council - Netherlands

In 1990, at the request of the Dutch government, the Dutch Health Council reviewed the scientific evidence on ETS to ascertain whether ETS is harmful to health. Although not entirely positive, the Council found the following:

- The evidence on ETS is mainly statistical and is beset by methodological problems.

- Occasional exposure to ETS is an inevitable concomitant of people's social lives.

- Quantitative estimation of the additional lung cancer risk of non-smokers exposed to tobacco smoke is not possible at present.

- On cardio-vascular disease: The Committee does not expect short-term exposure to tobacco smoke to affect the circulation of healthy non-smokers in normal circumstances.

- The Committee's conclusion that ETS is harmful to health is primarily based as a result of tobacco smoke's "smell and irritating effects".

EXECUTIVE SUMMARY

1 Introduction

This report is issued by a Committee of the Health Council of the Netherlands at the request of the Dutch government.

In order to ascertain whether environmental tobacco smoke is harmful to health, the Committee has evaluated the most important articles published prior to June 1990. It has also consulted two important American reports (USS86, NRC86). The Committee outlines its report below.

2 Evaluation of the results of epidemiological research

To evaluate the effect of exposure to environmental tobacco smoke one has to rely mainly on results of epidemiological research carried out among nonsmokers. This kind of research is beset by methodological problems which may distort the outcome. Distortion may be due to the following factors:

- the use of inaccurate measures of exposure and effect
- biased composition of the research groups to be compared (selection bias)
- bias of participants or researchers in reporting or compiling data (information bias)
- selective publication in scientific journals of results which indicate an effect (publication bias)
- the involvement of factors other than tobacco smoke (confounding factors).

The Committee examined the extent to which the published data might be distorted by any of the above factors. It used the

following criteria to assess whether exposure to tobacco smoke was a causal factor of the health effects found among nonsmokers:

- consistency of the results of various studies
- the magnitude of the increase in health risk as a consequence of tobacco smoke (the greater the increase, the greater the significance)
- the presence of a dose response relationship
- an appropriate time sequence of exposure and response (temporality)
- consistency with biological knowledge.

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3 Exposure of non-smokers to tobacco smoke

The tobacco smoke inhaled by a nonsmoker contains about 3,800 different substances. These include irritants, substances which can affect the nervous system, the respiratory tract, the immune system, blood and blood vessels and offspring, and also carcinogenic substances. The composition of directly inhaled smoke differs greatly from that of environmental tobacco smoke. Therefore the Committee considers it not possible to deduce from the health effects of active smoking to what extent exposure to environmental tobacco smoke causes effects in nonsmokers.

Exposure to tobacco smoke is widespread in the Netherlands. The Committee assumes that there are smokers in about six dwellings in every ten. In a survey carried out in 61 office buildings in the Netherlands, 41% of the nonsmokers questioned reported that tobacco was smoked in their immediate vicinity during working hours. Smoking considerably increases the indoor air concentrations of pollutants such as suspended particulate matter, nicotine, benzene, benzapyrene, nitrosamines and aldehydes.

In nonsmokers, traces of exposure to tobacco smoke are detectable in body fluids as certain substances, which include carcinogens and mutagens.

The Committee would point out that at present, occasional exposure to tobacco smoke is an inevitable concomitant

people's social lives.

Lung cancer

The Committee considers it likely that long-term exposure to tobacco smoke may increase the lung cancer risk of nonsmokers. This conclusion is based primarily on the results of a large number of surveys, in which the nonsmoking partners of smokers were found to have an increased lung cancer risk. By combining the various results, several authors have estimated that the increase in lung cancer risk might be between 10 and 60 percent. A number of studies have demonstrated a dose-response relationship.

The Committee considers an increase of the lung cancer risk to be biologically plausible since tobacco smoke contains substances which are carcinogenic in man and since the presence of tobacco smoke constituents or their metabolites has been demonstrated in the bodies of nonsmokers.

The Committee would emphasize that the apparent increase in the lung cancer risk could be partly due to flaws in the design of the epidemiological studies. As it is not known to what extent the results of the several studies are distorted, the Committee is of the opinion that quantitative estimation of the additional lung cancer risk of nonsmokers exposed to tobacco smoke is not possible at present.

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5 Other forms of cancer

On the basis of the epidemiological data currently available, the Committee cannot give an opinion as to whether exposure to tobacco smoke plays a part in the onset of cancer other than lung cancer in nonsmokers.

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6 Cardiovascular disease

The Committee does not expect short-term exposure to tobacco smoke to affect the circulation of healthy nonsmokers in normal circumstances. Nonsmokers with angina pectoris may occasionally experience symptoms in places with very high concentrations of tobacco smoke.

The Committee believes that the currently available data preclude a firm conclusion as to whether exposure to tobacco smoke is a contributory factor in the onset of and mortality from cardiovascular disease in nonsmokers. Epidemiological research carried out among nonsmoking partners of smokers provides only weak indications. The results of the several studies may have been confounded by differences in lifestyle between nonsmokers with and without smoking partners. So far researchers have not been able to control these differences adequately.

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7 Effects on children

The Committee concludes that exposure to tobacco smoke at home may have an adverse effect on children's health. The children of smoking parents run an increased risk of respiratory and middle ear infections. They may suffer more severely and more frequently from asthma and other respiratory symptoms. Development of the respiratory tract during childhood may be disturbed to some extent. In view of the association between the occurrence of chronic obstructive lung disorders in later life and respiratory disorders during the early years, the Committee does not exclude the possibility of long-term effects arising in children as a result of exposure to tobacco smoke.

In the opinion of the Committee, there is no doubt that smoking during pregnancy is harmful to the unborn child. Children of smoking mothers weigh less and are shorter on average at birth. The perinatal mortality rate is also higher. Although harmful substances from environmental tobacco smoke can pass through the placenta, it is not yet clear whether this can adversely affect the unborn children of nonsmoking mothers who regularly inhale tobacco smoke during pregnancy.

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8 Effects on the respiratory tract in adults

The Committee concludes that people with a disposition to asthma may be particularly sensitive to environmental tobacco smoke. They will suffer respiratory symptoms more fre-

quently at short-term exposure.

There are weak indications that adult nonsmokers who have been exposed for long periods to the tobacco smoke of smoking partners or colleagues experience respiratory symptoms more often than nonsmokers who are not similarly exposed. In addition, exposure has sometimes been found to cause a slight lung function decrease. The Committee believes that these indications do not yet permit a firm conclusion as to whether long-term exposure affects the respiratory tract. The effects found in surveyed groups of nonsmokers are small. It is not possible to ascertain whether these are the result of environmental tobacco smoke or other factors which have affected the respiratory tract, such as infections, illness, occupational circumstances or air pollution.

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9 Irritation and nuisance

Both smokers and nonsmokers may be bothered by tobacco smoke. People visiting smoke-filled places are at first overcome by the smell. This may be followed by irritation of the eyes and the mucous membranes of the nose, mouth and throat. Smell is the most sensitive nuisance indicator. The degree of ventilation needed to prevent nonsmokers from being hampered is much greater than that needed to avoid body odour nuisance. The latter serves as the general criterion for ventilation requirements.

The Committee believes that nuisance as a result of the smell and the irritating effects of tobacco smoke must be regarded as harmful to health. The continuous discomfort and the necessity to avoid public places constitute a fundamental assault upon a person's well-being.

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10 Summary from the health point of view

According to the health definitions laid down by the Health Council and the World Health Organization, it is not only the onset, aggravation or continuation of clinical symptoms or the reduction of life expectancy that are regarded as harmful to health. The extent to which the effects of ex-

posure to substances impinge on a person's ability to function normally is equally important (Gez77). In the opinion of the Committee, this principle also applies to exposure to tobacco smoke.

Short-term exposure to tobacco smoke can give rise to odour nuisance, irritation of the eyes and the mucous membranes of the eyes, nose, mouth and throat. It can also aggravate asthmatic symptoms. The Committee believes that such effects must be regarded as harmful to health in the light of the above principles. In the case of children, it takes the view that the effects of long-term exposure can be unequivocally regarded as harmful to health. The Committee also observes that the possibility of long-term exposure to tobacco smoke increasing the risk of lung cancer in nonsmokers cannot be excluded.

Section 2.2:

UK Government Response to Report on Indoor Pollution

Unfortunately, the UK government response to the House of Commons Report on Indoor Pollution (1991) did not consider the scientific evidence on ETS as objectively as the Netherlands. The government accepts that "breathing sidestream smoke causes a small increased risk of lung cancer.." (page 7).

The government recommends that non-smoking becomes the norm in the workplace and that separate, well ventilated areas be set aside for smokers. The government's policy is to promote workplace smoking policies and smoking restrictions in public places.

The Health and Safety Executive (HSE) will start a campaign on the need to segregate smokers and non-smokers in public buildings and will consider the need to update its current guidance on workplace smoking policies (page 5). We know that the HSE has already been pressuring important groups of employers to ban smoking completely in their workplaces.

If a similar report on ETS or IAQ exists in your country, please send me a copy at PMCS.

This UK report clearly illustrates one danger we are not always ready to counter. The danger exists that workplace smoking will be attacked through the national regulations of the safety and health agencies. The result, in the long term, will be similar to a legislated smoking ban, only governments will not have to face the political repercussions of such an unpopular law. Please make sure you have a good understanding of the position and actions undertaken by your national workplace safety and health agencies.